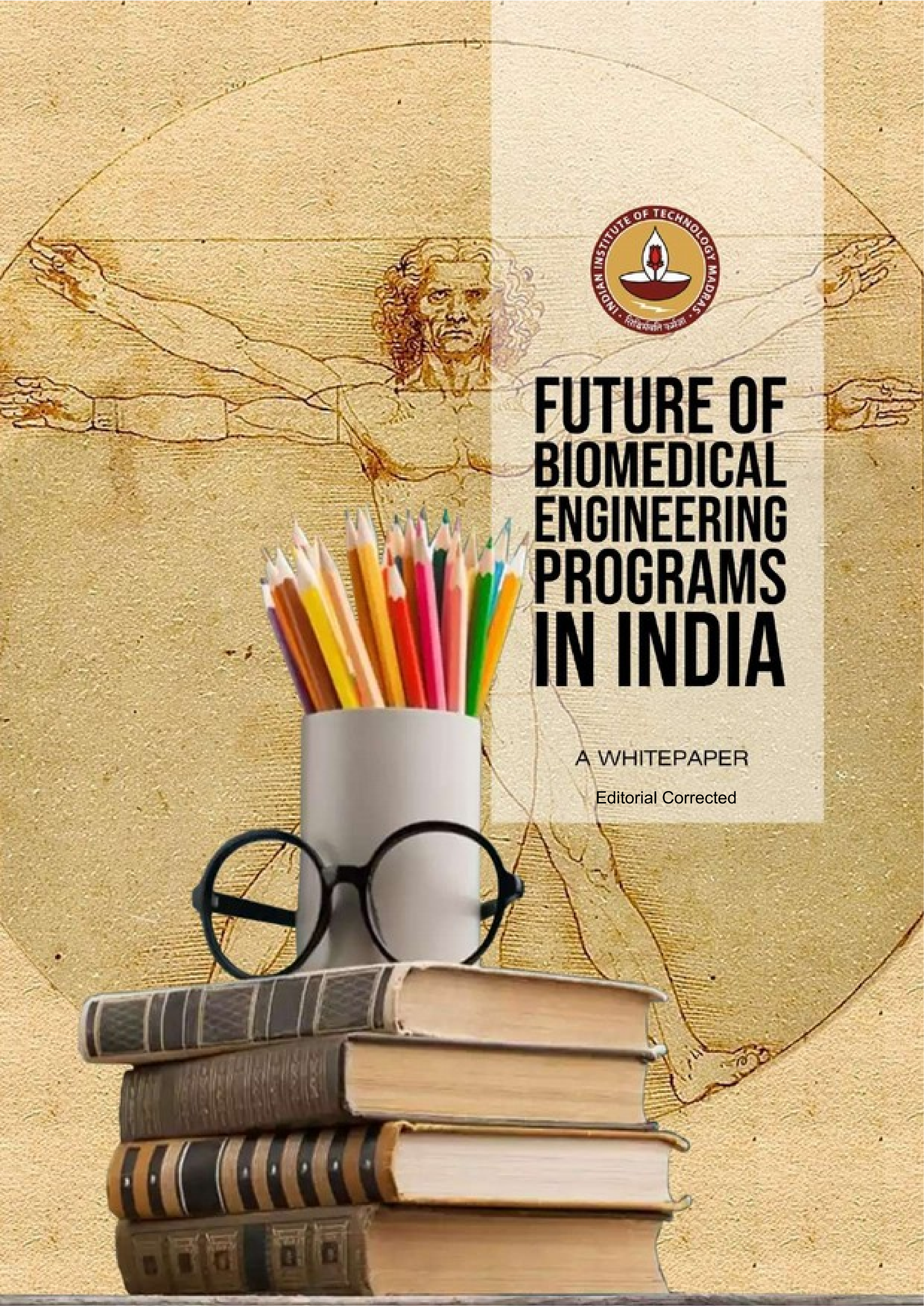

FUTURE OF BIOMEDICAL ENGINEERING PROGRAMS IN INDIA

A WHITEPAPER

Editorial Corrected

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26th February, 2021

FOREWORD

I am delighted to write the foreword for the whitepaper on Biomedical Engineering in India that Prof.M.Manivannan of IIT Madras and his team have compiled.

Delivering quality primary care and wellness care to large populations is a huge challenge for any country, particularly for India with the majority of population living in its villages. In order to address this challenge effectively, it is vital to develop human resources equipped with "scientific mind" and with a balanced mix of both medicine and engineering, virtue and good health by enhancing the whole cycle of education, from elementary schools to higher education. Towards this vision, Biomedical Engineering can play a vital role of bridging the gap between engineering and Medicine, seamlessly combining the design and problem-solving skills of engineering with medicine in order to improve healthcare diagnosis, monitoring and therapy, and ultimately wellness care.

Wellness care in India and traditional medicinal systems is one of the oldest in the world. India has the unique characteristic of having different well-acknowledged traditional systems of medicine. Biomedical Engineering along with these traditional medical systems towards Integrative Health System will make India a leader in providing healthcare not just for India, but for the entire world.

I am glad to note that the challenges faced by the Biomedical Engineering community in India are well documented in this whitepaper along with the recommendations to solve these challenges. We will do our best to address those challenges in the future.

I hope that this document will help the Biomedical Engineering community to deepen understanding of health from the holistic science and technology and provide best healthcare to everyone in India and the world. It is also my hope and expectation that this whitepaper will provide an effective referenced resource for all stakeholders of biomedical engineering and health professionals caring everyone specifically for infants and children, leading to improved wellness-care.

(Vinod K. Paul)

स्वच्छ भारत
एक कदम स्वच्छता की ओर

FOREWORD

Empowered by digital technologies and ubiquitous telecom networks, the demand for better biomedical devices and procedures is rapidly expanding not just in hospitals but in homes and on one's person. Fueled by this demand, the importance of biomedical engineering (BME) is growing worldwide. IIT Madras BME faculty is among the oldest biomedical engineering groups in India with diversity spanning several disciplines.

The IIT Madras Research Park, home to the Healthcare Technology Innovation Center (HTIC) and MedTech Incubator, along with a plethora of healthcare startups, is right next door to the campus and provides entrepreneurs access to our BME labs and faculty for fostering innovations in healthcare. Our Clinical Engineering program along with CMC Vellore and Sree Chitra Thirunal Institute of Medical Sciences is a unique program, while the Centre for Technology and Policy (CTAP) at IIT Madras focuses on healthcare policy. Recently, a new paper for BME was introduced in the GATE exam, which will set the standard for the BME curriculum in India. IIT Madras was among the key drivers in this initiative.

I am glad to note that this whitepaper on BME in India includes some snapshots of the work carried out over the years at IIT Madras. I congratulate Prof. M. Manivannan and his team for taking this important step of identifying the challenges in BME for greater acceleration of healthcare in India. India has great potential to be a global leader in providing frugal innovations in healthcare technologies, and I hope that this whitepaper will pave the way for the Biomedical Engineering community to serve society even better in future.

Bhaskar Ramamurthi
Director, IIT Madras

PREFACE

More than a decade, IIT Madras has been attempting to introduce a GATE paper for Biomedical Engineering. Only when Prof. Jagadeesh Kumar who is a pioneer in BME became the dean of academic courses at IIT Madras in 2017, the effort of introducing the new GATE paper gained momentum. The time was ripe in 2018 when IIT Madras became the GATE organizing institute under the chairmanship of Prof. Nilesh Vasa who is again a pioneer in BME sensors.

With both the BME stalwarts in the steering wheels at IITM, I was given the opportunity to take the efforts forward, first by organizing a meeting of all IIT BME faculty to discuss syllabus for the new GATE paper. We organized the meeting on 5th Oct 2018 for the first time to discuss the syllabus. The finalized syllabus was subsequently accepted and a new paper was introduced in 2019 when IIT Delhi was the organizing institute for GATE exams.

When we were discussing the syllabus for the GATE paper in the first meeting, we realized that the BME curriculum in India needs a total revamp. We found that the curriculum was totally lacking connection with the industries. This is when we realized that our responsibility was not merely setting the GATE syllabus, but also to make recommendations to all the stakeholders of BME in India for a successful transformation.

The inspiration for this whitepaper has come from another whitepaper "Strategies and A Road-map For Development of Instrumentation in India" by a committee constituted by Prof. M. S. Valiathan, then president of Indian National Science Academy, New Delhi, chaired by Dr. S. K. Sikka, Scientific Secretary, Office of the Principal Scientific Advisor to the GOI, published in June 2004.

The purpose of this current whitepaper is to help improve the quality of BME programs in India by identifying and addressing many challenges, bringing together all the stakeholders of BME in India.

For writing the current whitepaper, we interviewed several leaders of BME in industries, academia, government think-tanks, and other stakeholders. The highlight of the whitepaper is the recommendations for each of the stakeholders for the transformation in BME.

This whitepaper is an effort of many authors passionate about the BME transformation in India who have contributed in various stages of writing. Collectively, we all believe that the most important and productive approach to solving the current challenges facing BME is to discuss and to plan a common strategy for transforming BME education in India. This whitepaper is the result of this strong belief. We all hope that the government policy makers will consider the recommendations in this whitepaper for a mission-mode action in the near future.

M. Manivannan, IIT Madras

Lead Author and Editor,

5 May 2021

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Executive Summary

Planning for India's wellness care, rather than the illness-care, where 80% of the population is rural, is indeed a Himalayan task for the Government of India. As healthcare is becoming more and more instrumentation and devices-based, providing essential biomedical equipment to chosen centers, reaching remote corners of India, is challenging. Biomedical Engineering (BME) education system is the backbone of healthcare innovation in India. Unfortunately, the BME education system is hitherto ignored and needs special attention urgently.

Although India's BME educational system is developing for the past 50 years, its development has not accelerated enough compared to other programs in India.

As a first step in addressing major challenges of BME education in India, a new separate paper for Biomedical Engineering in GATE has been introduced from 2020. This is expected to unify the UG syllabus of BME among several universities and help stimulate BME research, product development, and Innovation in India.

Unless BME is strengthened carefully at this stage, our precious foreign exchange resources will continue to be wasted. Of paramount importance is the need to develop a robust indigenous BME industry and, in turn, BME education systems, the spine of the healthcare industry. The troubles and travails of Indian BME educational institutes and industries are discussed in workshops, and some remedies suggested in these workshops are enumerated in this whitepaper. The Government must extend its full support to this noble endeavor.

In a mission mode, India urgently needs dedicated and visionary BME institutes and programs that can breed scientists and engineers with in-depth training in medical and clinical sciences. Such trained people would function as independent investigators on important problems at the interface of engineering, technology, clinical medicine, and science, similar to faculty at Harvard-MIT Division of Health Sciences and Technology (HST), at the same time adapting the rich wellness heritage of India.

India has enormous potential and is poised for innovations from conceptions frugal, simple, and therefore affordable, leading the world in affordable wellness technologies.

Background

Biomedical Engineering

Biomedical Engineering (BME) is one of the more recently recognized disciplines in the practice of engineering. It is a highly interdisciplinary and upcoming field of technology around the world. BME has been described as the fastest-growing job market in the western world. The demand for BME engineers is growing at a rate of about 20% every year.

BME plays a vital role in a range of clinical fields, from diagnosis and analysis to treatment and recovery, and has entered the public consciousness through the development and proliferation of implantable medical devices, such as pacemakers and artificial hips, as well as the more futuristic technologies such as gene therapy, stem cell engineering and 3-D printing of biological organs.

The World Health Organization (WHO)[1] describes the work of biomedical engineers as follows: Trained and qualified biomedical engineers are needed for designing, assessment, regulating, maintenance, and management of medical devices present in health systems around the world. In response, the European Economic and Social Committee stated: "Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the products of biomedical engineering".

John Hopkin University Definition of BME: “Biomedical engineering education must allow engineers to analyze a problem from both an engineering and biological perspective, anticipate the unique difficulties in working with living systems, and evaluate a wide range of possible approaches solutions”.

The Biomedical Engineering program for UG/PG focuses on a strong foundation in mathematics, basic sciences, engineering, and life sciences. Biomedical Engineers will:

1. Continue utilizing and enhancing their engineering and biological training to solve health and healthcare issues globally relevant and based on scientifically and ethically sound principles.
2. Demonstrate leadership in their respective careers in biomedical engineering or interrelated areas of industry, government, academia, and clinical practice, and
3. Engage in life-long learning by continuing their education in graduate or professional school or through opportunities for advanced career or professional training.

Students' Outcomes in BME programmes[2]

“Currently, BME courses in India are defined in terms of their duration, syllabus, and content

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1 HUMAN RESOURCES FOR MEDICAL DEVICES The role of biomedical engineers, WHO Medical device technical series, 2015

2 https://www.bme.jhu.edu/undergraduate/objectives-outcomes/

(Content-based education). Clear learning objectives as to what students were expected to learn are still missing. On the other hand, Outcome-Based Education (OBE) is the approach where the students' abilities drive decisions about the curriculum by the end of the course. It provides an explicit statement of what the curriculum is setting out to achieve. The transfer of the education system from the traditional approach to Outcome-Based Education (OBE) had resulted in a significant improvement in many educational institutions worldwide. BME courses are optional for OBE due to their interdisciplinary nature”[3].

After completing a bachelor's degree in BME, students will demonstrate the ability in:

- Applying knowledge of mathematics, science, engineering, and medicine
- Designing and conducting experiments, as well as analyze and interpret data
- Designing a system, medical instrument, component, or process to meet desired needs with realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability
- Functioning on multidisciplinary teams
- Identifying, formulating, and solving engineering problems
- Understanding professional and ethical responsibility
- Communicating effectively
- Obtaining the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and societal context
- Recognizing the need for, and engage in life-long learning
- Gaining knowledge of contemporary issues
- Using the techniques, skills, and modern engineering tools necessary for engineering practice

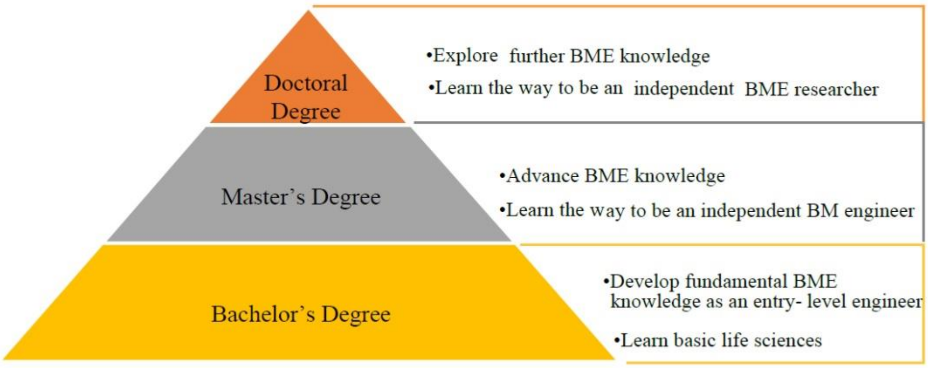
Program outcomes:

- Graduates must have the ability to apply knowledge of mathematics, science, engineering, and medicine.
- Graduates must have the ability to design and conduct experiments and analyze and interpret data.
- Graduates must have the ability to design a system, medical instrument, its components, or processes to meet the desired needs.
- Graduates must have the ability to function within multidisciplinary teams.
- Graduates must have the ability to identify, formulate, and solve engineering problems.
- Graduates must have an understanding of professional and ethical responsibilities.
- Graduates must have the ability to communicate effectively.
- Graduates must have the broad education necessary to understand the impact

of engineering solutions in a global and societal context.

- Graduates must recognize the need for, and the ability to engage in, life-long learning. J Graduates must know contemporary issues.
- Graduates must have the ability to use the techniques, skills, and modern engineering tools necessary for engineering practice.
- Graduates must demonstrate adequate knowledge of biology, physiology, and the capability of applying advanced mathematics (including differential equations and statistics), science, and engineering to solve the problems at the interface of engineering and biology.
- Graduates must demonstrate an ability to make measurements on, interpret data from living systems, and address the problems associated with the interaction between living and non-living materials and systems.

The difference between different levels of academic degrees in BME can be summarized as in the following diagram[3].



Biomedical engineers as human resources for health

BME is a field of practice that brings many, if not all, from the classical fields of engineering together to assist in developing a better understanding of the physiology and structures of the human body, to support the knowledge of clinical professionals in the prevention, diagnosis, and treatment of disease, and to modify or supplement the anatomy of the body with new devices and clinical services.

> "A key objective of biomedical engineers is to have devices that are of good quality, effective for the intended purpose, available, accessible, and affordable[4]. 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 to attain better care levels. The

3 Coates, J., & Takafumi, A. (2019). *Biomedical Engineering. Careers in Biomedical Engineering, 37–65.*doi:10.1016/b978-0-12-814816-7.00003-0

4 HUMAN RESOURCES FOR MEDICAL DEVICES The role of biomedical engineers, WHO Medical device technical series, 2017

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."

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 the delivery of health care in hospitals and other institutions, in academia, government institutions, and in national regulatory agencies."

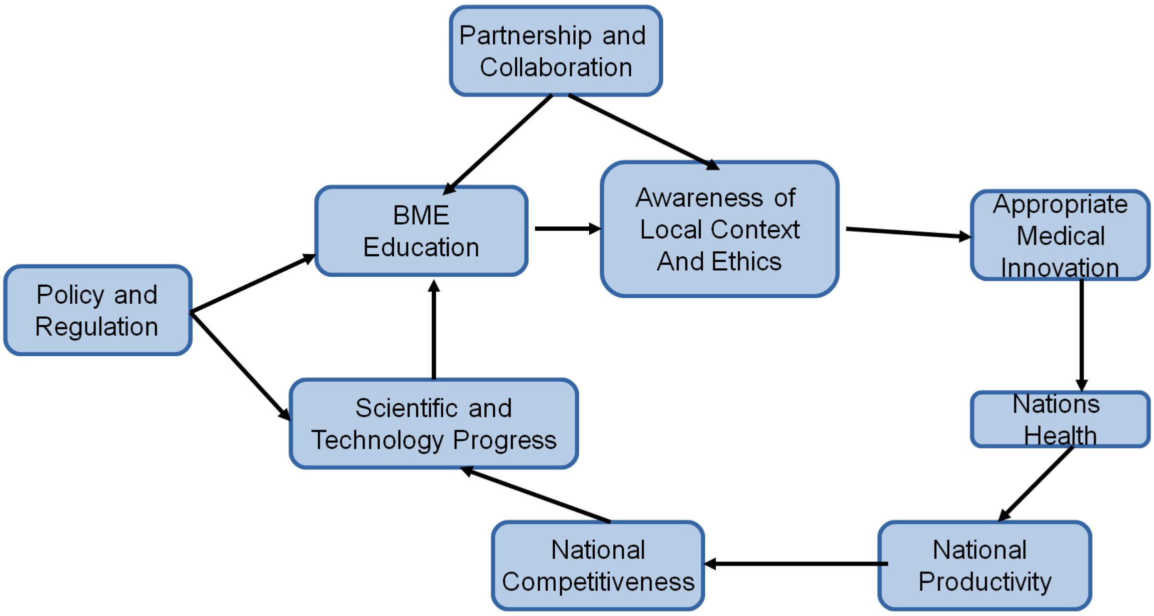
Importance of BME Programs in India

"The importance of BME programs is hardly noticed in India. India's medical device industry is presently valued at USD 5.2 Billion and is growing at 15.8% CAGR"[5]. Currently, India is counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China, and South Korea and is poised to grow to USD 50 billion by 2025. The medical device market is dominated by imported products, which comprise around 80% of total sales. Domestic companies are primarily involved in manufacturing low-end products for local as well as international consumption. Lately, many multinational companies have established local presence by acquiring established domestic companies or starting a new business.

As the Indian Medical Devices industry grows, there will be a need for biomedical engineering professionals. In the current scenario, the role of biomedical engineers is limited. Once high-end equipment is manufactured locally, there will be a surge in demand for skilled biomedical engineers.

BME programs are the backbone of the medical devices industry in a country. As long as the BME programs are not strengthened, any country would depend on foreign technologies for its healthcare technologies. The following figure shows how BME programs are the basis of the entire ecosystem of medical innovation.

5 http://www.makeinindia.com/article/-/v/sector-survey-medical-devices



Many variants of BME programs in India

BME includes equivalent or similar disciplines, whose names might be different, such as medical engineering, electromedicine, bioengineering, medical and biological engineering, and clinical engineering. The following list describes subtle differences between closely related terms with BME.

Medical Instrumentation: Bioinstrumentation or Medical Instrumentation specializes in the detection, collection, processing, and measurement of many physiological parameters of the human body, from more straightforward parameters like 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 developing and introducing modern imaging technologies such as ultrasound and magnetic resonance imaging (MRI).

Bioengineering: The profession named Bioengineering and/or Biological Engineering is younger than biomedical engineering and emerged with the realization of manipulating living cells. Bioengineering has engineering at its core and includes physics, mechanics, electronics, and computational methods applied to physiology and medicine.

Biological Engineering: 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.

Biomechanical Engineering: 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.

Clinical Engineering: Clinical engineers support and enhance patient care by applying engineering and managerial skills to healthcare technology, as described and elaborated by the American College of Clinical Engineering. Clinical engineers are trained to solve problems when working with complex human and technological systems of the kind found in health care facilities. Clinical engineers have the function of technological systems manager for medical equipment, including information systems in health care facilities. In hospitals, clinical engineers provide valuable feedback on the operation of medical equipment and contribute to the research and development from their direct experience. Often, they work in teams with nurses and other health professionals in the assessment of new concepts and products, as well as in clinical trials.

Rehabilitation Engineering: 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 enhance overall wellbeing.

There are few other programs closer to computer science applied in medicine and biology, resulting in developing newer research fields such as biomedical informatics, bioinformatics, and health informatics.

Stakeholders of BME Programs in India

Students are the key stakeholders of BME programs; others are

- Universities
- Colleges
- Teachers
- Parents
- Industries
- Governments
- Funding Agencies
- Hospitals

Why BME Programs Failed in India

Although BME was established in India way back in the 1970s, around the same period when the IITs were established, it has failed to attract the best students even after half a century of its existence in Indian colleges.

Lack of Integration

BME is underdeveloped in India mainly due to the lack of integration between research institutions, hospitals, industries, and universities in India. For example, clinicians and engineers work in isolation, not in collaboration. In developed nations such as the USA, UK, and Singapore, excellent integration exists between universities, industries, and hospitals, thereby creating the perfect environment for R&D in BME. This isolated working of the main stakeholders of BME in India led to several problems for graduates of BME programs in India, such as poor job market, lack of standard curriculum among the institutions offering BME programs, lack of fundamentals among the BME graduates, and several other issues. This scenario is changing, and India is likely to become the center of global healthcare research soon.

Lack of BME Jobs

In India, most of the jobs related to Biomedical Engineering are in non-tech areas such as service, maintenance, customer support, sales, and management. Students interested in pursuing a career in research and core development work in Biomedical Engineering look for jobs in universities, labs, and research centers in India or pursue MS and Ph.D. studies abroad.

The job scenario for the existing Biomedical engineers is discouraging, as presently, many of the Biomedical firms in India prefer electrical, electronics, or computer science graduates to Biomedical graduates. As a result of this, a BME graduate is either unemployed or forced to continue further studies or change the field to secure a job. Even the software industry, recruiting graduates of other allied branches of Electrical engineering is not considering Biomedical engineers in the campus recruitment. This indicates a wide gap between the needs of the industries and the undergraduate BME curriculum. To reduce the gap and make the curriculum industry oriented, the undergraduate curriculum needs to be modified by deleting the subjects that are found irrelevant and obsolete and incorporating relevant state-of-the-art subjects.

Lack of Local Interest

It is well known that engineering, particularly medical devices, is most successful when it caters to local design constraints and develops solutions for the local environment. BME programs in India should ensure that local perspectives are incorporated in a medical device design so that BME engineers can address the local needs and consider the constraints of impoverished communities in our environment. For example, BME programs in India are tailor-made to cater to the Medical Imaging needs of the country, as there are demands from MNCs in India.

Lack of Standard Curriculum

Biomedical engineering curricula have to adapt to the new needs and expectations of the future[6]. Unfortunately, In India, the curriculum has not changed in many years.

Plaguing BME Curricula in India

Biomedical engineering (BME) education in India is still in its infancy. Several Engineering Institutions in India have been offering undergraduate courses for decades now, and a few thousands of students have been conferred degrees. As the number of colleges and the number of students seeking to enroll in this program is continuously increasing, many more institutions are planning to start this undergraduate course.

Major problems with the BME programs in India are that

- No Standardization of BME syllabus in the UG: The curriculum is vastly different and has a varied focus.
- No catering to Industries or Hospitals: The curriculum is not designed to cater to the local industry or hospitals
- Hospitals in India do not need BME: The local policy does not require BME engineers to be consulted in the hospital setup. The hospitals do not see the value addition by the BME graduates.
- Industries in India do not need BME: Local industries do not see value addition by the BME engineers.

“The BME curriculum in India is poorly designed without a definite learning objective. In 1998, the National Science Foundation announced a competition for an Engineering Research Center in Bioengineering Educational Technologies. This center was awarded to a partnership led by Vanderbilt University that included Northwestern University, the University of Texas at Austin, and the Harvard/MIT Health Sciences

6 Jaime Punter-Villagrasa, Jordi Colomer-Farrarons, Francisco J. del Campo, Pere Miribel-Català, *Amperometric and Impedance Monitoring Systems for Biomedical Applications*, vol. 4, pp. 167, 2017.

and Technology Program (VaNTH ERC). This group identified several issues regarding education in biomedical engineering that they judged needed new effort or review. These were as follows[7]:

1. How can undergraduates be adequately trained in biology and engineering within the constraint of a four-year bachelor's degree program?
2. How can students be prepared for and be introduced to the actual practice of BME in businesses, industries, and health care organizations?
3. What academic organizations will foster BME education at all levels?
4. How should BME relate to other academic programs in engineering, health professions, and life science?
5. What are the roles of businesses, industries, and hospitals in BME education?
6. How can the unique complexities of BME be addressed—bioethical questions, complicated regulatory environment, rapid rates of obsolescence for graduates and teachers?
7. How can instructors cope with the minimal amount of teaching material for BME?
8. What are emerging biotechnologies, and how should they be taught?
9. How can realistic laboratory exercises be created?
10. How does one teach the more significant uncertainties in design inherent in technology aimed at living systems?
11. At the doctoral level, what should be the balance between training in biological and engineering science methodologies?"

All these issues are relevant to India as well and just as unaddressed. Few studies show that BME learning environments should be changed[8] , and they should be learner-centered, knowledge-centered, assessment-centered, and community-centered. Also, recent advances in learning technologies can help us to achieve this new learning environment with efficiency. Biomedical engineering educators can design and implement new learning systems that can take advantage of advances in learning science, learning technology, and reform in engineering education.

Higher Study Woes For BME Graduates in India

The lack of integration of BME stakeholders is mainly because of a lack of a standard BME curriculum. There is no consensus among the stakeholders on what to expect from BME graduates. There was no effort to standardize the BME curriculum in India. A new GATE paper in BME introduced in the year 2020 can make a difference in alleviating

7 Harris TR. 2001. Annual Report on the VaNTH ERC. http://www.vanth.org/ Annual Report3.pdf

8 Harris, T. R., Bransford, J. D., & Brophy, S. P. (2002). *Roles for Learning Sciences and Learning Technologies in Biomedical Engineering Education: A Review of Recent Advances. Annual Review of Biomedical Engineering, 4(1), 29–48.*doi:10.1146/annurev.bioeng.4.091701.125

some of these problems, if not eliminating them.

In recent times, the Graduate Aptitude Test in Engineering (GATE) has become the gateway for higher education and jobs in many government institutions (PSUs, DRDO Labs, ICMR Centers) in India and few educational institutes abroad. The GATE exam primarily tests the comprehensive understanding of various undergraduate subjects in engineering and science. Unfortunately, the BME graduates did not have a GATE paper until now and had to appear in several other subjects, which were not their strength. Therefore, they could not fare well in these tests, which led to a poor show in the job market, which reduced the quality of students opting for BME programs in a vicious cycle.

The subjects of interest in GATE for BME engineers were mostly two: IN (Instrumentation and Engineering) and EC (Electronics and Communication Engineering), closer to the BME curriculum. In other words, the Biomedical engineering syllabus is much different from IN and EC (electronics and communication). To appear in any of the two streams (IN or EC), BME graduates needed to prepare much more than their curriculum and compete with graduates from other streams in which the other students have specialized: there are many more colleges offering UG courses in IN or ECE. Therefore, the chances of BME students getting good ranks in GATE was very slim.

Before introducing the new GATE paper, most BME students appear in the IN paper rather than the EC paper in GATE. There are two reasons why this is so: 1) IN (Instrumentation and Control) is closer to the BME curriculum than the EC, 2) competition in EC paper is much more than the IN paper for BME students.

Only a tiny percentage (6%) of BME graduates who appear in the GATE (about 1000) could qualify. In 2017, 18,045 students appeared in the GATE in IN, and 2,190 qualified. BME students who appeared in the IN paper among the qualified ones are merely 27 (1.23%). In 2018, about 1024 students qualified in the GATE in IN paper, among them BME graduates are merely 28 (2.73%).

Students with "Control and Instrumentation (IC)" background were faring much better than BME students. Even though an equal number of students from BME and IC appeared in the IN paper of GATE, BME students lose out to IC. In 2017, the IN GATE paper was taken by BME (710), IC (896), however qualified ones were BME (27), IC (211). Similarly, in 2018, IN GATE paper was taken by BME (747), IC (880), however qualified ones were BME (28), IC (313). This shows that the IN GATE paper is biased to the IC candidates. Similarly, in 2017

1,41,177 took EC in GATE, and 19278 qualified; among them, merely 6 are BME candidates. In 2018, about 1,24,946 took EC in GATE, and 10898 are qualified; among them, merely 3 are with BME background.

> The challenges of BME graduates in India were discussed in a recent meeting at IIT Madras, organized by the Biomedical Engineering Group of Applied Mechanics Department, with representations from several IITs. It was decided to propose a new GATE paper for BME to solve some of the issues. The committee proposed a syllabus that emphasizes the fundamentals required for BME graduates. The proposal was approved by the National Coordination Board of GATE and scheduled to be implemented in 2020 onwards.

The new GATE paper enabled testing in some of the most crucial BME skills: Anatomy, Physiology, and human-machine interaction knowledge of Biomedical engineering. The new GATE paper would enable solving the problem mentioned above and letting GATE play a pivotal role in the growth of BME in India. A separate paper for BME in GATE would standardize the BME curriculum throughout India. Currently, each state has a different definition of BME and, therefore, its own curriculum.

> BME students appeared in many different GATE papers in 2020: BM(1486), BT(18), CS(2), EC(20), EE(3), GG(1), IN(49), MA(1), ME(1), ST(1), XE(16), XL(21). Out of these appeared BME candidates, only few are qualified: BM(38), BT(6), CS(0), EC(2), EE(1), GG(0), IN(8), MA(0), ME(0), ST(0), XE(8), XL[4). The GATE BM paper was taken by candidates from different degree disciplines: BME(1486), Biomedical Instrumentation(33), Biosciences(3), Biotechnology(9), Instrumentation and Process COntrol(3), Instrumentation Engineering and Technology(7). Out of these appeared candidates, the qualified ones are: BME(38), Biomedical Instrumentation(0), Biosciences(1), Biotechnology(0), Instrumentation and Process Control(0), Instrumentation Engineering and Technology(1).

The following figure compares the BME core and elective courses in few major universities in India.

CORE COURSES	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	TOTAL
Digital electronics & ICs	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	17
Engineering Mathematics	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	17
Anatomy & Human physiology	*	*	*	*		*	*	*	*	*	*	*	*	*	*	*	*	16
Bio materials	*	*	*	*	*	*	*	*		*	*	*	*	*		*	*	15
Micro processors	*	*	*	*	*	*	*	*			*	*	*	*	*	*	*	15
Biosensors & Transducers	*	*		*	*	*		*	*	*	*	*	*	*	*	*	*	15
Diagnostic & Therapeutic devices		*	*	*	*	*	*	*			*	*	*	*	*	*	*	14
Bio mechanics	*	*	*	*	*		*	*			*	*	*	*		*	*	13
Bio signal processing		*	*	*	*		*	*			*	*	*	*	*	*	*	13
Control systems	*	*		*	*	*	*				*	*	*	*	*	*		12
Medical Instrumentation	*	*	*				*	*		*	*		*	*	*	*	*	12
Network analysis	*	*	*	*		*			*	*	*	*		*			*	11
Medical imaging techniques	*	*	*	*		*					*	*		*	*	*	*	11
Hospital engineering		*	*	*	*	*	*	*			*	*				*		10
Biophysics	*	*		*	*			*	*		*			*	*	*		10
Signals and systems				*		*	*	*			*	*		*	*			8

POPULAR ELECTIVES	1	2	3	4	5	6	7	8	9	10
OOPs & data structures				*				*	*	*
Communication techniques		*		*				*		*
Tele medicine		*		*						
Artificial neural networks				*		*				*
Bio fluids and dynamics						*			*	
Medical informatics	*	*		*		*			*	*
VLSI Design				*						

1 - IIT -BHU	6 - Mumbai University	11- Visvesvaraya Technological University	16 - Ganapat University
2 - NIT Raipur	7- Pondicherry University	12 - Gujarath Technological University	17 - BPUT Odissa
3- Manipal University	8 - Rajasthan Technological University	13 - Bharathi University	
4 - A P J Abdul kalam Technological University	9 - I.K. Gujral Technological University	14 - West bengal University	
5 - Anna University	10 - Solapur University	15 - Osmania University	

Scope of this Whitepaper

This report mainly focuses on the undergraduate BME programs in India to describe the different roles that biomedical engineers in India can play and identify factors that determine the quality of biomedical education in India.

This publication addresses only the role of biomedical engineering education in developing, regulating, managing, training, and using medical devices, particularly undergraduate programs in biomedical engineering in India.

Aims and Objectives of this Whitepaper

This report aims to serve as a guideline for various stakeholders of BME education in India.

Three major objectives of this whitepaper are:

1) To list various challenges BME programs facing in India
2) To list unique opportunities for BME programs in India
3) To list recommendations for various stakeholders to improve the BME programs in India.

History of BME Programs in India

The practice of BME is not new in India. Ancient texts referring to Sushruta and his techniques of Rhinoplasty are widely known. However, in this document, we will refer to only the modern Biomedical Engineering programs developed after independence.

“Modern Biomedical engineering has been recognized in India for at least five decades. Technological developments have been in areas of importance to the country, with several groups actively involved in promoting bioengineering all over India. A group at the National Physical Laboratory has contributed significantly to ultrasonics and the development of piezoelectric transducers for other biomedical uses way back in the 1970s. Along with the BME group at IIT Madras, the Centre for Biomedical Engineering of IIT Delhi and the All India Institute of Medical Sciences is one of the country's first BME centers producing outstanding work in areas like instrumentation, rehabilitation, biomaterials, modelling, and analysis. Research in technology applied to reproductive physiology (an area especially relevant to India's needs) was initiated at this centre. Research at the School of Environmental Sciences, Jawaharlal Nehru University, has elucidated the effects and mechanisms of low-energy electromagnetic radiation and ultrasound on biological systems. In one of the school's projects, bone material for ultrasonic transducers and optical detectors was successfully demonstrated[9].”

Spearheaded by Dr. Sujoy K. Guha, the first national symposium on Biomedical Engineering was held in H. B. Technological Institute (HBTI), Kanpur in 1967, followed by the first national short term course on BME in 1968 at HBTI.

Chronological List of Institutes that started Biomedical Engineering programs in India

9 Med Biol Eng. 1969 Jul;7(4):457-9. Biomedical engineering in India. Guha SK, Krishnamurthy KS. PMID: 5359249

Institute	Year of establishment	Details
Institute of Aviation Medicine	1969	Biomedical Engineering Group
Electronic Radar Development Establishment	1970	Medical Engineers Group
IIT Madras[10]	1971	Biomedical Engineering Group in the Department of Applied Mechanics
IIT Delhi	1971	Biomedical Engineering Group
IIT Bombay	1988	Department of Biosciences and Bioengineering
Anna University	1998	Center for Medical Electronics in the Department of ECE
IIT Kanpur	2001	Department of Biological Sciences and Bioengineering
IIT Kharagpur	2001	School of Medical Science and Technology

IIT Madras

First Biomedical Engineering Division in India was established in IIT Madras and IIT Delhi in 1971. IIT Madras group was initiated by Prof. Danjoo Ghista, who returned from NASA to India. This division was expanded in 1972 to include four faculty with T. M. Srinivasan, K. M. Patil, and Megha Singh, along with S. Radhakrishnan. Many other institutions followed suit, with IIT Delhi emerging as an important centre in the North. Over the next decade, teaching and research, innovative medical devices, biomechanical concepts, and procedures were introduced in hospitals in and around Chennai[11]. They were: a stereotactic instrument to aid in brain surgery, rehabilitative aids, biofeedback procedures for neurological deficits, footwear for diabetic foot, functional electrical stimulation for drop foot, ultrasound instruments, optimization of correction in scoliosis, and cardiac support through counter pulsation theory, etc. were developed. Many of these were in use in hospitals around Chennai at that time.

10 Med Res Eng. 1972;11(6):19-25. Biomedical engineering at the Indian Institute of Technology (Madras)-I. Ghista DN.

11 Med Res Eng. 1980;13(2):23-6. Biomedical Engineering at the Indian Institute of Technology, (Madras)-II. Ghista DN.

IIT Delhi

“The Centre for Biomedical Engineering at IIT Delhi was established in 1971 at the same time as IIT Madras as a Joint venture of the Indian Institute of Technology Delhi and the All India Institute of Medical Sciences, Delhi. Sujoy Kumar Guha is the pioneer in Biomedical Engineering who founded the Centre for Biomedical Engineering, IIT Delhi, and AIIMS and obtained his MBBS degree from Delhi University. The Centre has applied engineering principles to address medical and biological problems. Over the years, the Centre has become a premier center in the country. On the 29th of Aug 2018, both the institutes signed a formal MoU for building a more robust Health Care system by Engineering and Technology interventions through 'cross-institutional interactions' between the two premier institutes."

IIT Bombay

“The Biomedical Engineering Group (BME) at IIT Bombay was set up in 1988. It is now a part of the Department of Biosciences and Bioengineering (BSBE). Biomedical Engineering is one of the youngest engineering disciplines and has made tremendous progress in the last four decades. This has been aided by rapid advancements in Semiconductor Technology, Information Technology, and Biotechnology. In Biomedical Engineering, researchers with expertise in diverse areas work towards the unified goal of creating products and techniques for better health care. The backgrounds of faculty in BME at IIT Bombay reflect the broad spectrum of expertise required to make better and more affordable health care a reality.

Further, the students admitted to the program have backgrounds in Engineering, Physical Sciences, Life Sciences, and Medicine, making it the only program in the country to offer M.Tech. Admission to such a unique mix of candidates. Creating a heterogeneous class composition promotes interaction between students and faculty of different backgrounds and provides research opportunities in exciting interdisciplinary areas.”

Anna University, Center for Medical Electronics

The Centre for Medical Electronics was established in 1998 in the Department of Electronics and Communication Engineering. The centre researches Medical Electronics and Biomedical Engineering and establishes collaboration with medical industries and hospitals.

IIT Kanpur

The department of Biological Sciences and Bioengineering was established in the year 2001 with the vision of conducting cutting-edge research and providing quality teaching and research training in basic biology, biomedical, and bioengineering fields. Their faculty and students come from various science and engineering disciplines and work in challenging problems that transcend science, engineering, and medicine boundaries.

IIT Kanpur is currently setting up a highly interdisciplinary School of Medical Research and Technology (SMRT), a medical school with Centres of Excellence (CoE) and a first-of-its-kind super-specialty teaching hospital in India. Combining medicine with engineering and encouraging cross-disciplinary learning, SMRT will provide an ecosystem that promotes the development of technology-based interventions for diagnosis, surveillance, management, mitigation, and prevention of diseases.

IIT Kharagpur

The School of Medical Science and Technology (SMST) was started at IIT Kharagpur in 2001 to provide a platform for interdisciplinary teaching and research in diverse medical science and technology areas. The School has collaborated with some of the best medical research institutes and medical industries worldwide. The School introduced an interdisciplinary three-year Master's Program in Medical Science and Technology (MMST) - the first of its kind in the country. Admission to the MMST program is granted to MBBS doctors each year based on the performance in an entrance test conducted all over the country. The School's MMST program is the only comprehensive physician-scientist training program in India that aims to bridge the gap that has historically separated biological sciences from engineering and physical sciences. The school also offers a 4-semester M.Tech program in (1) Biomedical Engineering and (2) Medical Imaging & Informatics. The School of Medical Science and Technology offers the following M.Sc. programs:- (1) MEDICAL PHYSICS (3YR. M.SC.) (2) NUCLEAR MEDICINE (2YR. M.SC.) in collaboration with Tata Medical Center, Kolkata, with AERB accreditation and (3) MOLECULAR MEDICAL MICROBIOLOGY (2YR. M.SC.)

IIT Hyderabad

IIT Hyderabad has one of the first dedicated departments for Biomedical engineering amongst the IITs in the country (est. 2010), focusing on technology development to address the country's healthcare needs with a substantial collaboration with the clinical ecosystem. IIT-H has been a trendsetter in academic education in the field. IIT Hyderabad integrates various disciplines like Biomedical imaging, nano, biotechnology, biomechanics, biomaterials, bioinstrumentation, biosensors, computational biology, biophysics, and neurotechnology under a single umbrella with a focus on translational research to create a formidable positive impact in healthcare infrastructure. With the aim of AtmaNirbhar Bharath in Medical Devices and Healthcare Technologies, IIT Hyderabad envisages training of Biomedical Engineers and researchers from the grassroots with a strong technology-oriented curriculum from the Undergraduate and above.

One of the first Bachelor's programs in Biomedical engineering from IITs has taken shape at IIT Hyderabad due to deliberations with multiple stakeholders to create well-equipped human resources who can take part in the research & development of medical devices and products. IITH has also been running successful Masters and Ph.D. programs in Biomedical engineering for more than ten years. Research is centered around problems through cutting-edge deep-tech solutions through strong clinical collaborations.

Unique BME programmes in India

School of Medical Science and Technology

"The School of Medical Science and Technology (SMST) was started at IIT Kharagpur in 2001 to provide a platform for interdisciplinary teaching and research in diverse medical science and technology areas. The School has collaborated with some of the best medical research institutes and medical industries worldwide. The School introduced an interdisciplinary three-year Master's Program in Medical Science and Technology (MMST) - the first of its kind in the country. Admission to the MMST program is granted to MBBS doctors each year based on the performance in an entrance test conducted all over the country. The School's MMST program is the only comprehensive physician-scientist training program in India that aims to bridge the gap that has historically separated biological sciences from engineering and physical sciences. The school also offers a 4-semester M.Tech program in Medical Imaging & Informatics."

Clinical Engineering Programme at IIT Madras

The M.Tech. (Clinical Engineering) program (MCE) at IIT Madras has an innovative approach of combining formal engineering programs with hands-on clinical exposure. It is a unique undertaking and utilizes the innate strengths and facilities of the three institutes – Sree Chitra Thirunal Institute of Medical Science and Technology (SCTIMST), IIT Madras, and Christian Medical College (CMC). These organizations together hold strong backgrounds in Technology, Biomedical Engineering, and Medical Sciences. The M.Tech. programme is of two years duration. The students attend courses and training at all three participating Institutes. The first semester is at IIT Madras, mainly undertaking courses. The second semester is at CMC Vellore, partly courses and partly clinical attachments. The third semester is at SCTIMST, partly courses and partly clinical attachments. In the fourth semester, the students undertake a project in any one or more of the three participating institutes, which is mostly translated into practice.

Stanford-India Biodesign

"Stanford-India Biodesign program is a fully-funded BME design program launched in 2007 as a first-of-its-kind collaboration between Stanford University, the All India Institute of Medical Sciences (AIIMS), and the IIT Delhi. The goal of the partnership was to identify and train the first generation of local innovation leaders in medical technology who, in turn, would help stimulate India's nascent medtech industry. It was operational until 2014.

Each year, four India fellows are selected to spend six months at Stanford working in multidisciplinary teams to learn and apply biodesign processes to real-world healthcare projects identified in Stanford's hospitals and clinics. The fellows then return to Delhi to repeat the process to address the unmet healthcare needs of Indian patients, physicians, and healthcare facilities and take their innovative solutions forward into patient care. Over the program's nine-year duration, Stanford-India Biodesign trained many innovators who developed few technologies and started a few companies."

The School of International Biodesign at AIIMS

"School of International Biodesign (SiB) is an innovation program implemented by the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India at AIIMS, New Delhi, and IIT Delhi in collaboration with QUT Australia and Hiroshima University, Japan. Since the inception of the program, DBT has engaged Biotechnology Consortium of India Limited (BCIL) to manage the techno-legal activities of this Programme. The current duration of this Programme is up to December 2020.

The mandate of this Programme is to train the next generation of medical technology innovators in India. The focus is on invention/innovation and early-stage development of affordable, accessible, and available medical technologies for our population.

More than 100 medical technology innovators (Doctors, engineers, designers, entrepreneurs) have been trained in the Biodesign process. This includes idea generation through clinical immersion, need-finding, need filtration at AIIMS, and prototype development at IIT, with IP generation with the help of BCIL towards developing innovative technologies for the country. More than 50 prototypes have been developed so far, which have been further refined, validated internationally, and tested (both preclinical and clinical trials).

This has led to the development of over 30 medical devices, which has been possible by young innovators, i.e., 60 Fellows and over 52 Interns who have been meticulously trained in the Biodesign innovation process by the faculty of AIIMS and IIT-D with international partners. These devices are built on more than 50 patents (National, International, and National phase filing). Fifteen technologies have been transferred, and twelve medical technology start-ups have been set up by the Fellows trained under this Programme in sync with the 'Start-Up' India Programme."

Medical device innovation program @ IIT Hyderabad

IITH is also the first IIT to start an exclusive MTech program on Medical Device Innovation that aims to provide the complete skillset to innovate in healthcare, which has become a trendsetter for other IITs to emulate and improve upon.

Visionary Institutes for Biomedical Engineering in India

Visionary institutes of BME breed physical scientists and engineers with in-depth training in medical and clinical sciences so that they could function as independent investigators on important problems at the interface of technology and clinical medicine, similar to the Harvard-MIT Division of Health Sciences and Technology (HST).

Although no such visionary institute exists in India, there are few exemplary attempts in India that harness the potential of Biomedical Engineering for immediate use in hospitals.

SCTIMST

"Biomedical Technology Wing at the Sree Chitra Thirunal Institute of Medical Sciences and Technology (SCTIMST), Poojappura, Trivandrum, dates back to 1973 when the Royal Family of Travancore gifted a multistoried building for the people and Government of Kerala. Sri. P. N. Haksar, the then Deputy Chairman, Planning Commission, inaugurated the Sree Chitra Tirunal Medical Center in 1976 when patient services, including inpatient treatment, got underway. At the Satelmond Palace, Poojapura, nearly 11 km away from this Hospital Wing, the Biomedical Technology Wing followed soon, again a gift by the Royal Family. The concept of amalgamating medical sciences and technology within a single institutional framework was regarded as sufficiently important by the Government of India to declare the center as an Institute of National Importance under the Department of Science and Technology by an Act of Parliament in 1980 and named it as Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. Dr. Manmohan Singh, the then Honorable Finance Minister of Government of India, laid the foundation stone of the third dimension of the Institute, Achutha Menon Center for Health Science Studies(AMCHSS), on June 15, 1992. Dr. Murali Manohar Joshi, the then Honorable Minister of Science and Technology and Human Resource Development, Government of India, dedicated the AMCHSS to the nation on January 30, 2000.

The Biomedical technology wing of the Sree Chitra Tirunal Institute for Medical Sciences and Technology has been instrumental in developing and commercializing technologies for several devices including, mechanical tilting disc heart valve prosthesis (an estimated 100,000 patients have been implanted with these heart valves), blood bags (annual production of nearly 40 million bags), membrane oxygenators, hydrocephalus shunts, vascular grafts, dental and hydroxyapatite-based bone materials."

CMC Vellore

"The Department of Bioengineering was started in Christian Medical College (CMC), Vellore, in 2003 to develop a platform to apply engineering knowledge to healthcare and medical research at the bedside. Bioengineering at CMC involves basic science and applied research in medical instrumentation, prostheses, mathematical analysis of physiological processes, biomechanics of musculoskeletal systems, motor control or learning, and neurorehabilitation.

The Bioengineering department in CMC works closely with several other departments in CMC. Our significant work has been in prostheses and assistive devices, EMG analysis, electrodiagnostic devices, and neurorehabilitation technology. The department has electronics and mechanical fabrication and testing labs and tools for embedded software development. Devices developed in the department are in use in several labs in CMC and other institutions. The Department conducts the Clinical Engineering program in collaboration with IIT Madras and SCTIMST, and Ph.D. program on Biomedical Devices."

IIT-Delhi and AIIMS

All India Institute of Medical Science (AIIMS) and Indian Institute of Technology Delhi (IITD) signed an MoU in 2018 for collaboration in BME education, research, and technology with an overall objective of building a more robust Health Care system through Engineering and Technology interventions through 'cross-institutional interactions' between the two premier institutes. The faculty of IIT Delhi are recognized as faculty of AIIMS, and this recognition catalyzes many biomedical research, which is otherwise a big challenge in India. It is expected that other institutes follow the same model as AIIMS and IIT Delhi.

IIT Madras

IIT Madras is known to make several first steps in India. In Biomedical Engineering also it has taken the following first steps.

1) The Biomedical Engineering Group in the Department of Applied Mechanics was started for the first time in India in 1971, along with IIT Delhi. Following this, many other institutes in India started biomedical engineering programs[12].
2) Clinical Engineering - M.Tech program is the first program in India specifically focussing on biomedical engineers for hospitals and developing allied technologies[13].
3) CTAP (Centre for Technology and Policy)[14] is a center for studying how Biomedical Engineering and technology policies can influence healthcare outcomes in India. The study includes many Biomedical engineering such as reproductive technologies, immunization engineering, simulation-based training, mobile health technologies, to name a few.
4) HTIC (Health Technology Incubation Center)[15] is an innovative incubation center where funding agencies, clinicians, and engineers create healthcare technologies.

Andhra Pradesh Medtech Zone (AMTZ)

To address the import dependency, the Andhra Pradesh Government set up the country's pioneer industrial park, Andhra Pradesh MedTech Zone (AMTZ), to bolster the manufacture of medical devices. AMTZ is also supported by key stakeholder Departments of the Government of India in its initiative to create a holistic ecosystem in the country for facilitating the growth of medical technology products in the country. The mission of AMTZ is to create a world-class manufacturing hub in the country for the medical devices sector and catapult India as a global destination of world-class medical technology products and provide easy and affordable access to healthcare products to the citizens of India. Medical equipment like thermometers to CT scan machines will be manufactured and tested within the zone. Its main objective is to manufacture medical devices at a substantially reduced cost of up to 40% by providing end-to-end services for the industry's operational needs, leading to a reduction in the country's huge import dependency.

AMTZ is an ecosystem for medical devices and houses institutions like Kalam Institute of Health Technology (KIHT), AIC – AMTZ MediValley Incubation Council, Biovalley Incubation Council, Indian Biomedical Skill Consortium (IBSC), and National Medical Devices Promotion Council. With World Class scientific facilities, covering centers for the excellence of 3D printing, Electromagnetic Interference & Electromagnetic Compatibility (EMI & EMC), Biomaterials, Materials Characterization, CT Scan

12 https://apm.iitm.ac.in/bio_medical.html

13 https://biotech.iitm.ac.in/academics/clinical-engineering/mtech-clinical-engineering/

14 https://ctap.iitm.ac.in/

15 https://www.iitm.ac.in/htic

Tube, Medical Lasers, MRI Superconducting Magnets, and Gamma Irradiation. This ecosystem is set to generate more than 20,000 employment opportunities. A large part would work in new biomedical engineering domains like production, product design, quality control, validation, and other areas.

Kalam Institute of Health Technology (KIHT)

Kalam "Institute of Health Technology (KIHT), supported by the Department of Biotechnology, Government of India, facilitates focused research on critical components pertaining to medical devices by supporting institutions involved with R&D and the transfer of technical knowledge for product development. It also guides market access and policy interventions required for the growth of the medical technology sector."

Living Legends of Indian Modern BME

Founders of BME in India were typically medical doctors raised in India but trained in advanced countries who wanted to bring modern medicine to the Indian masses. The goal of these living legends was not to make money through healthcare but to put healthcare within reach of all of India's citizens. Profit made it possible to do that, but it was not the end objective.

MS.Valiathan

M.S.Valiathan, as he is popularly known, awarded the Padma Vibhushan in 2005 for his contributions to health technology in India, can be best described as an intellectual wanderer par excellence. Indian BME history would remember him as the first physician-scientist of modern India who married medicine to technology, thereby bringing relief to many and enhancing national pride in medical devices and biomaterials. After his brief stint as a visiting faculty at IIT Madras, he set up the Biomedical Technology Wing of the Sree Chitra Thirunal Institute of Medical Science and Technology, Trivandram.

He was instrumental in building the prestigious Sree Chitra Thirunal Institute of Medical Science and Technology, Thiruvananthapuram, and acted as its founding director. During his tenure, the institute developed many Biomedical Devices, particularly the popular Heart Valve.

He is a strong proponent of the Indian Medical Systems, particularly Ayurveda.

Sujoy Guha

"Sujoy Kumar Guha is one of the founders of biomedical engineering in India; he is an electronics engineer from IIT Kharagpur; he later received his Ph.D. in medical physiology from St. Louis University. He then founded the Centre for Biomedical Engineering, IIT Delhi, and AIIMS and obtained his MBBS degree from Delhi University. Prof. Guha is internationally known in rehabilitation engineering, bioengineering in reproductive medicine, and technology for rural health care. He has received several awards and has more than 100 research papers in cited journals. In 2003 he became a chair professor at IIT Kharagpur and now an emeritus professor at IIT Delhi."

Dhanjoo Ghista

Dhanjoo Ghista was the Founding Head of the Biomedical Engineering Division, Department of Applied Mechanics, Indian Institute of Technology during 1971-1975. He has developed many noninvasive medical tests involving the Non-dimensional Physiological Index (NDPI), based on biomedical engineering formulations of organ function, physiological systems' functional performance, and anatomical structural constitutive property, the means for reliable medical assessment and diagnosis.

Future of BME abroad

"Biomedical Engineering programs are present at a large number of universities worldwide with an increasing trend. New generations of biomedical engineers have to face the challenges of healthcare systems worldwide that need a large number of professionals to support the present technology in the healthcare system and develop new devices and services. Health care stakeholders would like to have innovative solutions directed towards solving the world's problems, e.g., the growing incidence of chronic disease and the ageing population. These new solutions have to meet the requirements for continuous monitoring, support, or care outside clinical settings. The presence of these needs can be tracked through data from the Labor Organization in the U.S. showing that biomedical engineering jobs have the largest growth in the engineering labor market with an expected 72% growth rate in the period from 2008-2018. In European Union, the number of patents (i.e., innovation) is the highest in biomedical technology. Biomedical engineering curricula have to adapt to the new needs and expectations of the future"[16].

"Education in Biomedical Engineering has experienced changes also because of the research and development in the field, which was more intensive than in other fields.

Today, the labor market for biomedical engineers is not only research and development in institutes and at universities but also in industry and the health care system. Since medicine and health care have become highly specialized and

16 R. Magjarevic and M. L. Z. Diaz, "Biomedical engineering education — Status and perspectives," *2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, Chicago, IL, 2014, pp. 5149-5152. doi: 10.1109/EMBC.2014.6944784

technology-dependent and the public awareness for healthy life and wellness have risen, clinical and health centers need specialized professionals, not only for maintenance but also for operation, selection, and support to medical staff. However, primarily the BME industries and small and medium enterprises (SMEs), numerous spin-up companies need specialized professionals to transfer the technology from research to the clinical environment”[17].

Comparison Table of BME in India and other countries

	BME in Other countries	BME in India
1	The labor market for biomedical engineers is not only research and development in institutes and at universities but also in industry and the health care system.	The labor market for biomedical engineers is mostly for research and development in institutes and universities but poorly paid in the industry and the healthcare system.
2	Since medicine and health care have become highly specialized and technology-dependent and the public awareness for healthy life and wellness have risen, clinical and health centers need specialized professionals, not only for maintenance but also for operation, selection, and support to medical staff.	The Indian healthcare system depends on the CMC/AMC of the suppliers, not on the Biomedical Engineers.
3	The BME industries and small and medium enterprises (SMEs), numerous spin-up companies, need specialized professionals to transfer the technology from research to the clinical environment.	This segment is barely existent in India

Opportunities for BME in India

As the world's most populous country, India, with the dream of 'Health for All' serving the entire healthcare chain of disease prevention, diagnosis, treatment, and supportive care, medical devices face a Himalayan challenge.

Challenges:

“In rural areas (defined by the Reserve Bank of India as tier-3 to tier-6 cites <50,000

17 A.C. Villa, F. Urgilés, "Creation of the Biomedical Engineering Research Group GIIB-UPS at the Salesian Polytechnic University", Andean Region International Conference (ANDESCON) 2012 VI, pp. 185-187, 2012.

people), where almost 70% of the country's population resides, India's health system faces significant challenges to improve coverage and quality of care for its citizens. A low number of health care facilities and care providers, reliance on informal and private care providers, and high out-of-pocket costs are major barriers that need addressing"[18].

If India can be self-reliant in the Medical Technology sector and capitalize on this Medical revolution by ensuring all stakeholders play their respective roles, it would stand a good chance of realizing its vision of providing healthcare to all its citizens[19]. This requirement again leads to the urgent need to strengthen the BME education system as it is the backbone of medical science.

Lean resources, rather affordability, is a great motivator, which is not the focus in western countries. It produces an intense pressure to create value. The Indian hospitals pursue innovations in every facet of their operations, with a determination that is hard to imagine in rich countries, where medical resources are plentiful, and third-party reimbursement is the norm. In fact, India's meagre resources motivated many of the founders of our Indian exemplars to embark on their bold experiments in the first place.

Few other factors complicate the challenge further. The Indian population is huge, rural, largely price-conscious. Over this, India has to do with a severe shortage of doctors and facilities. Finally, the Indian healthcare industry is a wide-open market.

Opportunities:

Evolution of India as a Medical Tourism Hub: The government promotes medical tourism, stimulating a corporate boom in medical care. This has resulted in India emerging as a medical tourism hub for patients from all over the world. International tourists who come to India specifically for medical treatment demand high-quality care and world-class equipment, leading to private care providers upgrading their medical technology infrastructure.

Growing Awareness on Advancements in Medical Technology: Urban Indians

"18 SMARThealth India: A stepped-wedge, cluster randomised controlled trial of a community health worker managed mobile health intervention for people assessed at high cardiovascular disease risk in rural India. Peiris D, Praveen D, Mogulluru K, Ameer MA, Raghu A, Li Q, Heritier S, MacMahon S, Prabhakaran D, Clifford GD, Joshi R, Maulik PK, Jan S, Tarassenko L, Patel A. PLoS One. 2019 Mar 26;14(3):e0213708. doi: 10.1371/journal.pone.0213708. eCollection 2019. PLoS One. 2019 PubMed citation PMID:30913216"

19 Finally, the MedTech industry in India should embrace the path of innovation so that its products and solutions are tailor-made for the opportunities and constraints of the country.

are becoming increasingly aware of the latest medical technologies available in the market and are consequently demanding the same. Industry members are also conducting seminars and workshops to make people more aware of the technology available, and this awareness has increased demand for new medical technologies.

“India's medical devices industry is growing at about 15 percent annually. It is expected to reach at least $25-30 billion (Rs 1.65-1.98 lakh crore) by 2025, according to a report in March by Deloitte Touche Tohmatsu India, driven by indigenous manufacturing, exports, and local innovation. However, the industry is fragmented, price-sensitive, and faces constraints such as erratic power supply, low doctor-patient ratio, and a shortage of trained personnel to handle complex devices, pain areas, and startups trying to tide over achieve market acceptance.

The affordability and increased reach that these startups bring are also particularly crucial. According to Deloitte, medical technology contributes significantly to healthcare delivery costs in India, with medical devices and diagnostics accounting for 20-25 percent of the cost of medical services.

Finally, India's MedTech industry should embrace the path of innovation so that its products and solutions are tailor-made for the country's opportunities and constraints, specifically for rural India”[20]. For embracing the path of innovation, innovation needs to be inculcated, and therefore BME education needs to be strengthened in that aspect.

Impact of indigenous biomedical instruments

Few examples of Indigenously developed Biomedical Instruments and their impact on the Indian Economy

Jaipur Foot

The Jaipur Foot is a low-cost prosthetic limb developed by Dr. P.K. Sethi and implemented in clinics across India and the world. The Jaipur Foot, developed in 1970, is low-cost, light, and mobile. Those who use it can run, climb trees and even pedal a bicycle. While an artificial limb can cost several thousands of dollars in the US, the Jaipur Foot costs only $30 in India.

The Jaipur Foot was developed at the SMS Medical College Hospital, Jaipur, in 1968, by a group of eminent orthopaedic surgeons and a highly innovative

[20] CII Report, Medical Technology: Shaping Healthcare For All In India”, 2017. https://www.cii.in/Publicationform.aspx?PubID=56695&ty=pub

craftsman. The first scientific publication on the Jaipur Foot was by Dr. PK Sethi, director and professor of rehabilitation, SMS Medical College, Jaipur; Dr. SC Kasliwal; Dr. MP Udawat; and master Ram Chandra.

“Although the design was developed to meet the socio-cultural needs of disabled people in India — with their unique needs for a prosthetic that would permit them to squat, sit cross-legged, walking on uneven terrain, work in wet, muddy fields, walk without shoes, and so on — it has proved to be a 'universal design.' It can interface with prosthetic technology used around the globe.

The Jaipur Foot distinguishes itself from other artificial feet by not having a central keel, thus permitting mobility in all planes despite being non-articulated. The dorsiflexion at the ankle, a unique feature of the foot, addresses the cultural and lifestyle needs of Oriental people; however, this positively influences the performance of amputees even in Western societies.

Its performance has transcended geographical boundaries and is being used by disabled people in over 40 countries worldwide. It is the most widely used prosthetic foot in the world”[21].

The impact of the Jaipur Foot was pertinently described in Time magazine (fall 1997 issue) thus: "People who live inside the world's many war zones from Afghanistan to Rwanda may never have heard of New York or Paris, but they are likely to know a town in Northern India called Jaipur. Jaipur is famous in strife-torn areas as the birthplace of an extraordinary artificial limb known as the Jaipur Foot that has revolutionized life for millions of landmine amputees."

TTK-Chitra Valve

“A mechanical heart valve developed at the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum, India, is available in the market as TTK Chitra heart valve prosthesis model TC1 since 1994[22]. The TTK Chitra TC1 model valve has been used in more than 100,000 patients by now. Feedback from various clinical follow-up studies and post-market surveillance studies indicate that linearized occurrence rates of para valvular leak and haemorrhage are relatively low. Many studies also show low to moderate levels of thromboembolic events. In general, the clinical results are comparable to any other mechanical heart valves in the market.”

21 jaipurfoot.org/how_we_do/technology.html

22 https://journals.sagepub.com/doi/full/10.1177/0954411917703676?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed#

Aurolab's Intra-Ocular Lenses (IOL)

"Aurolab, based in Madurai, a famous city in the southern part of India, is an integral part of the Aravind Eye Care System. When Aurolab was started in 1992, its first product was Intraocular Lenses (IOLs) when its import price was around $80–$150 per piece. Few Indian manufacturers could make a high-quality lens and the few that did charged a high price. Alcon, a U.S.-based manufacturer, was the world leader with a nearly 50% share of the approximately $1 billion market for IOLs.

> Aurolab, with its lower manufacturing and distribution costs combined with its philosophy of making eye care affordable, was able to initially price the IOLs at around $10–$12. Aurolab's IOLs were tested at U.S. laboratories and compared with the best of similar U.S. Food and Drug Administration (FDA)-approved IOLs. However, to get the FDA approval, much more work and expense were necessary because of the requirement to demonstrate the effectiveness in live human trials of representative populations. Aurolab chose to invest its scarce resources in scaling up production rather than in clinical trials. It was, however, soon able to get the European Union's CE mark, which only required demonstrating product equivalency[23]."

GE's Revolution ACT

"GE's Revolution ACT is the first 'Made in India' CT (computed tomography) scanner, an advanced yet affordable device that is transforming how trauma, stroke, and other conditions are managed in India. The installations are from markets outside of metro and tier-I locations like Kumbakonam in Tamil Nadu, Purnea in Bihar, Daund in Maharashtra, Midnapore in West Bengal Medak in Telangana, many of which never had access to this technology.

> In global markets, the Revolution ACTs is approved to sell in more than 50 countries, primarily in South Asia, Africa, ASEAN, Asia Pacific, and Latin America. In Vietnam, for instance, since the installation of the Revolution ACT in 2016 at The National Lung Hospital in Hanoi, there has been an increase in case load of 40-50 patients per day, using 40% less electricity, less space, and lower dosage radiation, for a fraction of the cost of a traditional 16-slice CT[24]."

Kalam-Raju stent:

23 https://healthmarketinnovations.org/sites/default/files/Aravind,%20Process%20Evaluation.pdf

24 https://www.livemint.com/companies/news/-centre-of-gravity-for-innovation-has-gradually-shifted-to-growth-markets-1551985746972.html

"India's first indigenous coronary stent was developed in collaboration with Mediciti Hospitals, Hyderabad. Cardiologists widely use coronary stents to dilate constricted arteries for treating heart attacks. The stent is fully indigenous, including the capital machinery used for its fabrication which, in turn, has been manufactured by the collaborator's parent company. The main objective behind developing these stents was to substantially bring down the cost and make it affordable to the commoner. The stent, known as the Kalam-Raju stent, underwent satisfactory clinical trials. Subsequently, nearly 2000 stents were implanted in the next few years at the cost of Rs.15,000/- each as against the then market price of Rs 40-60,000 for a comparable imported stent[25]."

Sahajanand Medical Technologies

"Sahajanand Medical Technologies (SMT) was born in 2001. The Company became one of the first companies in Asia to develop and manufacture coronary stents. Headquartered in Gujarat indigenously, SMT is the largest developer and manufacturer of precision-engineered cardiac products in India. The Company has a comprehensive product portfolio, including coronary stents (drug-eluting and bare-metal), renal stents, PTCA balloon catheters, and other cardiac accessories in India and abroad. Over 500,000 stents are used in India every year. A cardiac stent is a device used to unblock clogged arteries. Drug-eluting stents are coated with medicines that help lower the recurrence chances of an artery narrowing after corrective surgery. SMT is the largest stent maker in the country, with a market size of more than 22% in a highly fragmented market dominated by foreign players."

Smart-Cane

"Supported by the Wellcome Trust, the Smartcane project has revolutionized how visually challenged persons could navigate the world. They face great difficulty in independent mobility and use the white cane as a mobility aid to detect close-by obstacles on the ground. However, the cane has two major limitations: It can only detect obstacles up to the knee level. Hence, the user cannot detect raised obstacles like elevated bars and frequently collides with them. The cane can only detect obstacles within 1m from the user. Also, obstacles like moving vehicles cannot be detected until dangerously close to the person. Almost 90% of blind people live in developing countries, with a majority below the poverty line. Current devices available internationally are unaffordable. This work presents the design and usability features of a low-cost knee-above obstacle detection system and reports results from controlled field experiments.

Use of directional ultrasound-based ranging to enhance the horizontal and vertical range of the cane. System designed for ease of use at an affordable cost. To assess the reduction in collision-risk and personal safety improvement

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25 http://www.sbmtindia.org/activities/kalam_raju_coronary_stent/

with the unit, controlled trials with 28 users were performed.

A lightweight, detachable unit consisting of an ultrasonic ranger and vibrator was developed, which offers an increased range of 3m and detects obstacles above knee level. Distance information is conveyed to the user through vibratory patterns that vary incrementally with changing obstacle distance. The projected cost of the device is under 35 USD making it affordable for users in developing countries. Smartcane is the most affordable obstacle detection system globally to improve independent mobility for the visually challenged[26]."

DBT-AMTZ COMManD Strategy

DBT-AMTZ COMManD strategy is, therefore, a three-pronged approach that has been put in place by the support of the Department of Biotechnology (DBT), GOI, and the ecosystem support of AMTZ, to ensure that rapid infrastructure capabilities are used for progressively improving the manufacturing capabilities of domestic manufacturing in the medical technology sector in a rapid and quality assured manner.

Kudos to the Indian government's health emergency and disaster management proactive approach and ground zero dynamics based strategies, from abysmal domestic medtech manufacturing base, AMTZ has led to a quantum jump in medtech production capacities towards three objectives of securing more human lives, health technology for all (medtech self-sufficiency) and conserving much needed economic resources needed in a long drawn fight again CoVID 19. Thus 360-degree perspective of DBT-AMTZ COMManD strategy encompassing all possible medtech & diagnostic wherewithal at CoVID 19 battlefronts. This is probably the only one-stop integrated and comprehensive solution in the world towards pandemic management.

The outcomes of COMManD Strategy: Current Monthly Production Capacity

- One Crore Diagnostic kits /day across all Test Formats (RT-PCR, ELISA & VTM)
- 1,000 / day Infra red non- touch thermal scanners
- 3000 PPE kits per day
- 1,00,000 (N95) masks per day
- 3000 Ventilators per month
- 5 mobile I-labs per month

Catering to 50% of daily national requirements of diagnostic kits. The current production capacity is likely to be scaled by 300-500% in the next two quarters to cater to global demands and enhance the capability to fight CoVID 19.

26 Rohan, Paul et al. "'Smart' Cane for the Visually Impaired: Technological Solutions for Detecting Knee-Above Obstacles and Accessing Public Buses." (2007).

Vision for BME programs in India

Exponential Technologies

BME is an interdisciplinary field that advances knowledge in engineering, biology, and medicine. It enhances people's health through multi-disciplinary actions that merge all engineering disciplines with the biomedical branch and clinical practice. Most Biomedical engineers have been training in physiology and medicine, in addition to in engineering. Today thousands of medical instruments have taken part in the hospitals and little care centres. These modern devices facilitate the diagnosis and treatment of diseases of the patient's condition. Thus, the major area of biomedical engineering is covered by the healthcare sector. Combining health care with Exponential Technologies such as Artificial Intelligence (AI), 3D Printing, Virtual and Augmented Reality, Drones, Robotics, Data Science, and Autonomous vehicles provides a broader outlook for this emerging BME field. BME and Exponential technologies together can provide solutions to many modern problems. However, the approach requires collaboration between government institutes, various funding agencies, and private partnerships.

Medical Devices Park in Every State

Another evolving domain could be the manufacturing sector that lies with the national vision "Made in India." The Medical Devices Industry in India is the 4th largest in Asia and among the top 30 in the world. It is a highly capital-intensive industry and boasts immense potential in terms of skilled manpower and research & development. Initiatives like Make in India and Atmanirbhar Bharat Abhiyaan have given a much-needed thrust to manufacturing medical devices in the country. To further promote domestic manufacturing and develop related infrastructure, the Government of India has approved the following schemes: Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices and Promotion of Medical Device Parks.

Academic Liaisons and Industry Partnerships

To fulfill this evolving field's expectation, there is a need for making liaisons between different academic institutes with the hospitals such as IIT Roorkee with the AIIMS Rishikesh, or IIT Delhi with AIIMS Delhi. The vicinity of the place and the talent nurtured in the top-ranked institute would drive the collaboration to its near future end goals. The logistics planned to connect every other industry and institutes such as NITs or central universities combining hospitals with the online tracking for the project proposal to research execution offers some solutions. For instance, managing medical waste by researching in collaboration with environmental activists and the industry as CSR could solve problems that occur due to contamination of extremely dangerous communicable viruses.

Physiological Database for BME in India

Oil does not determine the economy anymore. It is 'data' now, specifically health data. India is the second-most populous country with so many different cultures and variations. BME stakeholders need physiology data from their citizens for either learning or validating new instruments. So far, we depend on physiological databases abroad such as PhysioNet at MIT that includes collections of cardiopulmonary, neural, and other biomedical signals from healthy subjects and patients with a variety of conditions with major public health implications, including sudden cardiac death, congestive heart failure, epilepsy, gait disorders, sleep apnea, and aging. It is critical to set up our database for the following reasons:

- Strengthening the collection of local population health data in India will be critical to address public health challenges in the country if done securely and transparently.
- This is an era of personalized medicine, also referred to as precision medicine, that separates people into different groups based on many health parameters, including race, predicted response, or disease risk.

Indian Medicine and BME Programs in India

Modern Instruments for Indian Medicine

Unlike modern medicine, the concept of Life is central to Indian Medicine (IM), such as Ayurveda, Siddha[27]. Life, according to IM, is a continuous union and combination of *Shariram, Indriyam, Satvam,* and *Atma*. Modern science could not provide a satisfactory definition of what life is. Life has been defined in a hundred different ways. However, there is currently no consensus regarding the definition of life that considers all the dimensions of life.

Unfortunately, quantitative measurements in Indian Medicine (IM) are scarce. Most IM studies use qualitative measurements instead of quantitative measurements. This may be either due to lack of instruments specific to IM, or different kinds of perspective IM has on the human system, or maybe due to a combination of both reasons. Whatever the reason be, quantitative measurements are needed in this competitive, aggressive modern world.

No modern instruments have been developed for objective measurements of these life-related concepts IM. In many instances, the IM researchers overcome this lack of instruments by using the measuring instruments available for modern science. This has caused many IM issues because IM and modern science have differing views of

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27 M.Manivannan, Novel Measuring Instruments for Indian Medicine: Wholesome Concepts, Annals of Ayurveda Medicine 9 (4), 251-255

nature or objects.

Biomedical Engineering in India can play a significant role in bridging this lack of instruments in IM. Some of these instruments could be:

- Measuring instruments for Panchabhootham
- Measuring instruments for Prakruthi
- Measuring instruments for Taste
- Measuring instruments for Human Body Heat
- Measuring instrument for Human Breath
- Modern DIagnostic Instruments for IM

IM researchers need measuring instruments for measuring life. To achieve this, we need visionary organizations dedicated to the development of these measuring instruments. This can breed IM scientists and IM engineers with in-depth training in IM medical and clinical sciences to function as independent investigators on important problems at the interface of wellness, engineering, technology, clinical medicine, and science, adapting India's rich wellness heritage. A central organization similar to the “Central Scientific Instruments Organization (CSIO)” for IM instruments could be formed.

IM needs a highly interdisciplinary team to adapt and use recent advances in sensors and computing power to design and develop novel measuring instruments. Indian Institutes of Technology (IITs) can play a major role in marrying modern scientific technologies and IM.

IM researchers with sound fundamentals are the need of the hour. IM fundamentals could even be introduced in school and engineering curricula. Simple interesting experiments based on IM principles can be designed and introduced in school and engineering laboratories. Degree programs in “IM Engineering” such as “Siddha Engineering” and “Ayurveda Engineering” can be designed and introduced in major institutes such as IITs.

Incubation centers for developing systems for IM would stimulate innovations. Like the Biotechnology Industry Research Assistance Council (BIRAC), IM Innovation Research Assistance Council could encourage entrepreneurs to contribute to IM research.

Modeling and Simulation for Indian Medicine

Simulation and modeling are important tools in engineering that solve real-world problems safely and efficiently. They provide an important method of analysis that is easily verified, communicated, and understood. Across industries and disciplines, simulation modeling provides valuable solutions by giving clear insights into complex systems. The complexities of modern biomedicine are rapidly increasing.

Thus, **modeling and simulation** have become increasingly **important** as a strategy to understand and predict the trajectory of pathophysiology, disease genesis, and disease spread in support of clinical and policy decisions.

Modeling and simulation can enable IM practitioners to improve their services in diagnosing, treating, understanding, predicting, designing novel medicine, and testing and validating.

There is a compelling need to solve complex social, both at the national and international level. AYUSH integrated biomedical problems that are crucial to human welfare and society in general. That requires more broadly trained scientists with multi-disciplinary perspectives that include all engineering departments, particularly physical, mathematical, humanities, electrical, mechanical, civil, computer sciences, and design.

Exponential Technologies for Indian Medicine

Next Generation AYUSH Healthcare systems with a focus on prevention / early detection and proactive therapy can employ exponential technologies (AI, Big Data, Blockchain, Sensor Technology, Synthetic Biology, Tissue Engineering, Robotics, 3D Printing, etc.) that will undoubtedly lead to significant changes in the way we experience, think about, and deliver healthcare and in which a digitally empowered patient will play a more important role.

Technologies for Skills Training in Indian Medicine

Realizing the importance of modern clinical education practice, NMC has mandated skills labs in every medical institute. The purpose of these **skills lab** is to provide a safe environment for students to learn, practice, and observe performing skills in a simulated environment with patient-like mannequins, thus mitigating the risks for the patients arising out of treating them without adequate preparation and supervision.

Similar technologies for skills training can be promoted for Indian Medicine such as Siddha and Ayurveda. Such technologies will help in standardising and scaling the training for skills in Indian Medicine. For example, mannequins for Naadi diagnosis training, one of the essential skills in Indian Medicine, will be very useful.

Recommendations

The BME education system in India needs a revamp. The following suggestions are to improve the system, listed for several stakeholders of the BME.

Recommendations to Universities and Colleges

Currently, BME courses in India are defined in terms of their duration, syllabus, and content (Content-based education). A clear statement as to what students were expected to learn was not on the agenda. On the other hand, Outcome-Based Education (OBE) is the approach where the students' outcomes drive decisions about the curriculum by the end of the course. It provides an explicit statement of what the curriculum is setting out to achieve. The education system's transfer from the traditional approach to Outcome-Based Education (OBE) has significantly changed many educational institutions worldwide. BME courses opt for OBE due to its interdisciplinary nature[28].

Apart from the engineering concepts, biomedical engineers need a strong understanding of physiology and cell biology. The focus should be on building the fundamentals of these concepts, not the advanced topics. Advanced topics can be pushed to either the final year or at the master's level.

The following are the highlights of revamp in BME education system:

- Encourage clinicians to teach courses or participate in research Incentives for clinicians to work in Engineering colleges
- Incentives for BME Teachers to work in Medical Colleges and participate in their research
- MoU’s with Hospitals, medical colleges, Working closely with Doctors, Real-world clinical problems.
- Encourage collaboration between the hospital and educational institutes as AIIMS-IITD. Encourage industrialists to teach courses or participate in research through
  -Incentives for industrialists to teach in Engineering colleges
  -Incentives for BME Teachers to work in industries and participate in their research
  -MoU’s with industries, Working closely with industries, Real-world industrial, clinical problems

One of India's main problems now is the gap between Universities’ education and industries’ need. . Bridging this gap could solve a lot of problems. To solve this problem, create an Advisory board for the BME program: This board Provides feedback to the BME department that helps to forge the program’s policies and objectives, update the objectives according to the demands. The board may comprise members, doctors, directors, and managers from several health industries and biomedical Institutions. This board should be regarded as the most important primary constituent of formulating and adjusting the program.

Internships in Industries and hospitals should be part of the curriculum even in

28 Abdulhay E, Khnouf R, Haddad S, Al-Bashir A. Improvement of medical content in the curriculum of biomedical engineering based on assessment of student outcomes. *BMC Med Educ*. 2017;17(1):129. Published 2017 Aug 4. doi:10.1186/s12909-017-0968-2

the early years of the program:

Entrepreneurship as a part of the curriculum: Encourage students to form a virtual biomedical engineering company with an up-to-date topic of interest. At the end of the course, the students should be ready to start their own company, if they are interested.

Institutes can offer industry-sponsored scholarships for preparing BME students for specific industrial needs. When the students graduate, the Industry that is sponsored can be given the first choice to recruit the students.

There is intense pressure on educational institutes to continuously adapt their objectives to face new requirements and challenges in both market demands and R&D programs. In 2017, the government of India approved the National Health Policy, which envisages the realization of quality health care through both promotive and preventive practices. The BME curriculum needs to be updated according to the national health policy, constantly depending on these demands.

Buzz words such as Artificial Intelligence, Machine Learning, Virtual Reality, Blockchain can be given as options (elective courses) to the BME graduates, but the emphasis should be on fundamentals.

Modern BME Applied to Indian Medicine Systems such as AYUSH may be necessary for the coming days. A rigorous scientific approach to AYUSH is therefore essential, which in turn needs special instruments for AYUSH. Indian Medical Systems needs new instruments. Without these instruments, AYUSH cannot be scientifically validated from their perspectives.

The lack of regulatory systems, harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices, etc., are affecting the medical devices industry adversely. This could be emphasized in the BME curriculum.

The hands-on experience of a BME graduate should be emphasized as a part of the curriculum. At least one course should be made compulsory emphasizing hands-on which should include essential basics.

Challenges	Recommendations
Graduates not ready for hospitals or BME industries	-Collaborate with hospitals and BME industries -Design curriculum in discussion with hospitals and BME industries -Include Clinicians and Industrialists as member of the Board of Studies or Board of Programs -Conduct promotions through associations with training institutes, summer programs, or winter programs -Encourage Summer Internships and Winter Internships -Encourage final year projects in the hospital setting or

	industrial setting
BME engineers are not competent	-Add practical aspects to the curriculum -Focus on aspects that are relevant to hospitals and industries. Hospitals need calibration, maintenance, evaluation of new equipment. -Focus should be on the fundamental principles that go into the design of most hospital equipment.
Weak BME curriculum	-Design and execute an Integrated BME program where engineering and medicine faculty are both involved in shaping the BME engineers, -Strengthening the BME Systems will enable India to produce stronger BME Leaders and Entrepreneurs. With most of our Health Equipment in both Hospital and Home Care imported into the country, an integrated program would enable a larger pool of BME Leaders and potential entrepreneurs across India to ensure that Make in India goes beyond Software and Services into Products Hardware.

Recommendations to Teachers of BME subjects

The focus should be on the fundamentals of the BME subjects, not on the latest topics. Once the students are thorough with the fundamentals, they can learn advanced topics by themselves.

Invite clinicians from medical colleges and industrialists to teach a few guest lectures in your courses. Furthermore, provide incentives for the guest lectures.

As BME is an outcome-based program, encourage course projects in each of the courses. The students should be encouraged to do small projects emphasizing the principles taught in the course. The teachers should provide resources for the students to undertake such projects.

Recommendations to Students of BME programs

A strong interest or passion for understanding and solving problems in Medicine is of paramount importance, without which any amount of training in academia or industries is of no use. Therefore, courses in cell and molecular biology, physiology, and basic medicine are an absolute must. Fundamental concepts in the core course in undergraduate should be the focus, not advanced topics. Advanced topics will be easy only when you master the basic concepts.

Most PSUs in India use GATE scores for employment. With the new GATE (BM) paper, BME students can be competitors to other branch students for

PSU jobs. Most PSUs will require BME candidates in the future, and the field BME is emerging; for example, ISRO aims for human-crewed missions that require BME.

IITs provide opportunities for BME graduates in the following programs:

- Offer two-year M.Tech in BME.
- Offer research-based M.S. Program.
- Offer direct Ph.D. programs for Undergraduate students.
- Offer summer internships in their laboratory, for two months, specifically during May-Aug for third-year BME students
- Project Associateship is a project-based position. This position can lead to conversion to a master's program or Ph.D. program.

Other Scholarships for the Students:

- The Kishore Vaigyanik Protsahan Yojana (KVPY) is a National Program of Fellowship in Basic Sciences, initiated and funded by the Department of Science and Technology, Government of India, to attract exceptionally highly motivated students for pursuing introductory science courses and research careers in science. BME students are encouraged to make use of this.
- Junior Research Assistantship, Senior Research Assistantship are project positions in any of the academic institutes.

Avoid Projects in Project Centers

- Unlike other engineering courses, BME is a highly outcome-oriented course. Therefore, BME students should desist from undertaking their final year projects in Project Centers, instead of undertaking themselves in their colleges.

Focus on Internships:

- BME students should give Internships the utmost importance (at least one). It should emphasize on experiencing and learning from the industrial problem. To gain better skills, students can focus on more than one internship.

Recommendations to BME Industries

There is a big disconnect between BME institutes and industries in India. BME Education is the backbone of the healthcare ecosystem.

Quality is of paramount importance for medical products. Indian industries are currently focussing on affordability, not on quality. For long, India has struggled to provide quality, affordable healthcare to all its citizens[29]. Instead of the

[29] https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html

conventional route, for disruption and affordable quality, the focus should be on innovation rather than indigenization. For innovation, BME education should be strengthened. A certain percent of the industry's income could be spent on R&D activities, as consultancy projects to educational institutes.

India's strength in local traditional medical systems, focusing on wellness, prevention rather than cure, could focus on disruptive innovation.

Medical Technology provides a massive opportunity for both the educational institutes and the industry to work synergistically. It can bridge the distance between the caregiver and the patient, thereby helping patients remotely access specialist and specialized equipment present in large cities far away. Technological advancements in health monitoring and diagnostics help detect health issues early on, reducing the overall cost of care and enhancing society's wellness levels. Similarly, technological interventions rapidly increase the precision and efficacy of treatment modalities, thereby improving clinical outcomes. To realize this opportunity, both the educational institutes and the industry will need to make concerted efforts.

The educational institutes should streamline the training in a manner that makes graduates ready for the industry. The industry needs to customize its business models to suit Indian markets. Medical device segments that provide sizeable opportunities and require a moderate level of technical expertise should be prioritized for manufacturing in India. Finally, India should embrace the path of innovation in the MedTech industry that makes its products and solutions tailored-made for the country's opportunities and constraints[30].

Industries can sponsor scholarships in educational institutes for preparing students for specific industrial needs. When the students graduate, the Industry that is sponsored can be given the first choice to recruit the students.

If India can be self-reliant in the Medical Technology sector and capitalize on this Medical Technology revolution, which could be achieved if all stakeholders play their respective roles, it would stand a good chance of realizing its vision of providing healthcare to all its citizens[31].

Industries can recruit BME graduates specifically for R&D by making sure that the graduate is very strong in the fundamentals and much interested in the research career and scientific publications.

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30 https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html

31 https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html

Challenges	Recommendations
Disconnect with academia	-Academia creates graduates ready for industry -Academia creates programs specific for a BME industry -Setup Academia Advisory Board with well-known personalities -Sponsor a scholarship for creating one or two graduates ready for your industry -Sponsor summer internship and offer industrial problems to be solved by the summer interns -Provide incentives for academicians and clinicians to be part of industries
Lack of Quality	-Quality is foremost important -Use design principles to improve quality. -Invite international collaborations
Lack of Innovation	-Focus on wellness: prevention rather than cure -Install medical device-specific scholarship in educational institutes
Lack of self-reliance in medical device	-Bring all the stakeholders together -Encourage a BME consortium that brings all the stakeholders together, similar to automobile consortium

Recommendations to Policymakers in Government

As BME education institutes are the medical device industry's pillars, BME education and training could be included in the National Medical Device Policy proposed to strengthen the Medical Devices sector. Medical device-specific scholarships could be instituted in various educational institutes at various levels of students and scholars: undergraduate, graduate, doctoral, and post-doctoral.

> For a successful medical device and instrumentation program, we need to bring three key players together: Engineering Faculty, Clinical Faculty, device Industry, and create an ecosystem in which these three key players can collaborate. All projects related to Medical Devices in India could be insisted to have these three players.

Without collaboration with medical hospitals and medical colleges, BME programs would not serve their purpose. Therefore, Medical college faculty should be given incentives to participate in engineering college programs actively. As of now, the medical college faculty and clinicians are busy attending to patients and teaching medical students. They could be encouraged to interact with students of BME.

There are no institutes dedicated to Biomedical Engineering in India. These interdisciplinary institutes can integrate Biomedical Engineering, Science, and Technology (BEST) and medicine (BEST-MED) for local needs. Few mission-oriented BEST-MED institutes can be created.

In parallel with incorporating anatomy and physiology in biomedical engineering programs, medical education could incorporate one or two courses on engineering principles. Traditionally, medical research and practice have not included the principles and techniques used in engineering. The differences in the educational programs and cultures between medicine and engineering led to their dichotomy, with relatively few interactions. Initially, one course on Engineering principles could be introduced to medical students in the early formative years of their education[32].

Many engineers are deeply interested in studying medicine, and many doctors want to study engineering. While western countries allow engineers to become doctors and doctors to become engineers, it is impossible in India. Allowing this cross-discipline is one of the ways to improve the BME innovation ecosystem in India.

With wellness and prevention as the focus of India's current medical policy, medical devices need to be developed to achieve these noble goals. Prevention principles which are plenty in AYUSH could be taught in BME engineering colleges, as AYUSH Engineering (AYUSH-E) and modern medical devices and instruments specifically for AYUSH-E could be developed.

Just as automobile industries have made significant progress in India, device developments can be a mission mode. A medical device corridor can be designed to achieve self-reliance in medical devices. Similar to the automobile consortium, a medical device consortium can be promoted.

Public procurement of Medical Devices under the Public Procurement (Preference to Make in India) Order (PPO), 2017 provides preference to Make-In India programs[33]. However, this policy does not mention the role BME institutes can play and the teamwork between the technological institutes and the medical universities.

The affordable mantra is acceptable but must cater to the medical community's

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32 Chien S, Bashir R, Nerem RM, Pettigrew R. Engineering as a new frontier for translational medicine. *Sci Transl Med*. 2015;7(281):281fs13. doi:10.1126/scitranslmed.aaa4325

33 Department of Pharmaceuticals' Notice available at: http://pharmaceuticals.gov.in/sites/default/files/Guidelines%20for%20implementation%20of%20Public%20procurement. pdf

needs without compromising quality. While encouraging indigenous development, and therefore affordability, quality must be emphasized. Encouraging the BME education system in India could achieve this.

Set up a BME development committee with representatives from the Medical devices industry and academia of engineering and medicine. The committee would:

- Identify BME skill gaps and reduce shortage
- Design curriculum and explore possibilities for online/ e-learning modules to meet the specific requirement of the medical device segment
- Engage with affiliated Vocational Training Providers as well as potential ITIs, Polytechnic and other institutes for skill development
- Set up satellite educational centers and training campus around manufacturing hubs for skill upgrading
- Liaise across the Medical devices industry for job placements
- Provide counseling to BME candidates seeking skill development and address issues like student loans, scholarships, job placements, etc.

A committee for Curriculum on undergraduate BME to be setup:

1. Emphasize curricula rooted to research in the respective departments - students directly get involved in cutting edge research and project activities that prepare them for industry
2. A nation-wide standardized curriculum beyond the basic courses (first 2 years) might not be advisable as different centers have different core expertise; programs should be able to tap into them freely
3. Integrate hands-on Medical devices programs into the undergraduate curriculum
4. Build open-courseware on regulatory processes, standards, medical device rules for different geographies:
   Invest in faculty development programs and teaching modules to train BM engineers on the critical aspects of such processes
   Focus on highly critical standards and rules such as IEC/ISO/MDR/BIS
   Online certification programs through NPTEL on these processes to sensitize the BM community
   Actively participate in drafting
   Standards and regulatory
   Medical device rules and BIS standards
   Health Technology Assessment

1. Request for government/industry support to build and maintain full-compliance facilities for certification of cutting edge medical technologies
2. Define roles of Biomedical Engineers in industry, clinics, interdisciplinary research, and Start-up ecosystem through discussions with stakeholders and re-align curricula with NEP-2020 as a reference point
3. Participate in international Exchanges

Challenges	Recommendations
Lack of local talent	-Promote Industry-Academia Partnership, encourage international collaboration for promoting R&D in India -Promote teamwork between engineering and medical universities -Promote teamwork between AYUSH and engineering
Lack of Innovation in BME	-Spur innovation by increasing the budget for soft loans and grants -Allow cross-discipline BME programs -Provide incentives for clinicians and medical institutes to work with engineers
Lack of India specific Medical device	-Few mission-oriented BME institutes dedicated to medical devices can be created. -Install medical device-specific scholarship in educational institutes -Make every project in medical devices sponsored by the Government of India to include engineers, clinicians, and entrepreneurs.
Lack of self-reliance in medical device	-Bring all the stakeholders together in a BME Consortium -Encourage a BME consortium that brings all the stakeholders together, similar to automobile consortium -Install outcome-based scholarships

Recommendations to Funding Agencies

One of the major challenges in BME research in India is finding the right resource for a hard-to-solve problem. Social networking can be harnessed to solve this issue. To enhance interdisciplinary research by enabling individuals to connect and with resources throughout the nation, a Web-based database similar to the VIVO is a social networking site that enables connections among the geographically dispersed scientific community.

> A research media tool specific for Indian Biomedical Research could be implemented similar to VIVO, an open-source software system for research discovery. Originally developed at Cornell University, VIVO was enhanced through a large NIH ARRA award to a consortium of seven schools led by the University of Florida. VIVO provides an open information model for representing scholars, their works, funding, data, and research resources.

A tool for sharing information among the funding agencies could be developed. Many funding agencies fund the same project due to the lack of a shared database of funded projects, which may be by different applicants or by the same applicant.

Allocate 5% of the funding of each project for consultation with educational institutions. BME industries need collaboration with educational institutes and R&D labs.

Every project should have a clinical partner and an entrepreneur as PI in the project. BME projects need clinical validation. Without the involvement of clinical doctors, the projects may not see the market.

For disruptive products, the focus should be on innovation rather than indigenization. For innovation, BME education should be strengthened. A certain percentage of the industry's income could be spent on R&D activities, as consultancy projects to educational institutes, just like CSR funds.

Set up a BME Skill development committee with representatives from the Medical devices industry, academia, and Healthcare Sector Skill Council (HSSC) under National Skill Development Council (NSDC). The committee would Identify skill gaps and reduce shortages for the medical device industry.

Recommendations to Hospital Management

There is a big disconnect between BME institutes and hospitals in India, a much bigger disconnect than industries. BME Education is the backbone of the healthcare ecosystem. Some measures need to be taken to reduce this disconnect.

Given that prevention is better and cheaper than treatment, hospitals in India could and should focus on the rapidly growing market for monitoring and screening medical devices for both communicable and non-communicable diseases. This, in turn, emphasizes the focus on technology, and therefore BME educational system in India.

Encourage BME internships in hospitals, with unique goals of improving quality and affordability. Furthermore, encourage students with stipends and awards for the internships and can arrange an assessment session at the end. This assessment can be taken seriously and the assessment report of that particular student can be submitted to the supervisor at the University/College. Moreover, hospitals can provide options to pursue final year projects to those who completed internship with them, and can consider even for a placement based on the performance.

As the awareness and quality of healthcare increase, Indian hospitals will increasingly feel the need to hire BM graduates to oversee the technical side of instruments, develop new procedures, etc. If this happens, and even if only tertiary-care hospitals begin to employ BM graduates / PGs, we would still be looking at a requirement of a few hundreds of BMEs.

Work with BME institutes for preparing BME graduates adding value to the hospital environment, maybe by offering a scholarship, internship, or even going for placements.

Recommendations to NMC (MCI)

As healthcare and wellness-care become more instrumentation and device-based, the role of BME is critical for quality care in hospitals, from preparing quotations/tenders, maintaining records EMR or equipment history, setting standards and ensuring compliance, to advising & providing expertise to the medical staff & administration, and hospital's safety committee. Such a critical role of BME could be mandated as an NMC (MCI) norm for hospital accreditation. The number of BME required for each hospital could be determined by the number and value of these instruments in the hospital and several other factors.

To ensure the quality of these biomedical engineers in hospitals, they can be mandated to pass the newly introduced GATE paper in Biomedical Engineering.

Recommendations to Bureau of Indian Standards (BIS)

The Bureau of Indian Standards (BIS) is the national Standards Body of India working under the Ministry of Consumer Affairs, Food & Public Distribution, Government of India. It is established by the Bureau of Indian Standards Act, 1986, which came into effect on 23 December 1986. Indian Standards are formulated through specialist technical committees (functioning under the Division Councils), namely, Sectional Committees, which may be supported by other technical committees like subcommittees and panels set up to deal with specific subjects. Medical Equipment and Hospital Planning (MHD) is the division council that deals with medical devices and healthcare services, so Biomedical Engineers play a very important role in formulating the medical devices' standards. Hence, it is very important to recommend Biomedical Engineers to BIS.

Appendix A: List of Incubators for Biomedical Engineering Healthcare Tech

State	Incubation Center
Andhra Pradesh	Medivalley Incubation Council, AMTZ, Vizag.
	Biovalley Incubation Council, AMTZ, Vizag.

Bihar	Medical Electronics Incubation Center, IIT Patna
	Bihar Entrepreneurs Association (BEA)
Goa	Centre for Incubation and Business Acceleration
Gujarat	Atal Incubation Center - Gujarat Innovation and Startup Center Foundation
	Centre for Entrepreneurship Development (CED)-A
	CIIE IIMA
	iCreate
	DA-IICT
	Indian Institute of Technology Gandhinagar (IITGN)
Haryana	Society for Innovation & Entrepreneurship in Dairying (SINED) Technology Business Incubator
	Veddis Ventures
Jammu & Kashmir	SMVDU TBIC
Karnataka,	NITK–STEP
	Incube Ventures
	MICA Incubator
	Venture studio center for innovative business design
	Technovate
	NDBI (NID Incubator)
	Composite Technology Park - (TBI)
	Bio-Incubator at C-CAMP
	Prime Venture Partners
	Indavest
	Khosla Labs
	Nadathur S Raghavan Centre for Entrepreneurial Learning (NSRCEL)

	Srijan Capital
	Manipal University Technology Business Incubator
Kerala	TIMed MedTech Incubation Center, SCTIMST
	Technopark TBI
	Amrita TBI
	Maker Village Cochin
	CET – Technology Business Incubator
	Startup Village
Maharashtra	Biomedical Engineering and Technology (Incubation) Center, IIT Bombay
	NCAIR - National Centre for Aerospace Innovation and Research
	MITCON Biotechnology Business Incubation Centre (MITCON)
	D.K.T.E. Society's Textile & Engineering Institute
	Seedfarm, Seedfund
	SINE
	UnLtd India
	Sardar Patel Technology Business Incubator
	Venture Center
	Science & Technology Park, University of Pune
New Delhi	IAN Incubator
	Shriram Institute for Industrial Research
	Technology Base Incubator Society (TBIS)
	FITT

Odisha	Technology Business Incubator, KIIT University
Punjab	STEP, Thapar University
Rajasthan	Startup Oasis
	TBI, BITS Pilani
Tamilnadu	IIT-M Incubation Cell (IITM-IC)
	TREC-STEP
	Periyar Technology Business Incubator
	PSG-STEP
	Rural Technology and Business Incubator (RTBI)
	Sathyabama University-Technology Business Incubator (SU-TBI)
	Forge
	VIT- Technology Business Incubator
	Technology Business Incubator Centre for Biotechnology
	BIT-TBI, Sathyamangalam
	SPEC-TBI
	Vel Tech – Technology Incubator
	Villgro
Telagana	IIIT-H Foundation
	Life Science Incubator at IKP Knowledge Park
	Wadhwani Centre for Entrepreneurship Development
	IIT Hyderabad Incubator
	Progress Software's Incubator
	Association for Innovation Development of Entrepreneurship in Agriculture (A- IDEA)
	Centre for Entrepreneurship Development (CED)
Uttar Pradesh	Information Technology Business Incubator(ITBI), JSSATE- STEP

	TBI-KIET Group of Institution
	SIDBI Innovation and Incubation Centre (SIIC)
	Malviya Centre for Innovation Incubation & Entrepreneurship
	SIDBI Innovation & Incubation Center
	advantEdge
	Amity Innovation Incubator
	Technology Business Incubator, Graphic Era University, Dehradun
West Bengal	CSIR-IICB BIOMEDICAL INNOVATION CENTER
	IITG – Technology Incubation Centre (IITG-TIC)
	Science and Technology Entrepreneurship Park
	Technology Incubation and Entrepreneurship Society (TIETS)
	Ekta Incubation Centre
	WBUT
	IIM Calcutta Innovation Park

Appendix B: GATE Syllabus for BME

“Section 1: Engineering Mathematics

Linear Algebra: Matrix algebra, systems of linear equations, Eigenvalues, and Eigenvectors. Calculus: Mean value theorems, integral calculus, partial derivatives, maxima and minima, multiple integrals, Fourier series, vector identities, line, surface, and volume integrals, Stokes, Gauss, and Green’s theorems. Differential equations: First order equation (linear and nonlinear), higher-order linear differential equations with constant coefficients, method of variation of parameters, Cauchy’s and Euler’s equations, initial and boundary value problems, solution of partial differential equations: variable separable method. Analysis of complex variables: Analytic functions, Cauchy’s integral theorem, and integral formula, Taylor’s and Laurent’s series, residue theorem, solution of integrals. Probability and Statistics: Sampling theorems, conditional probability, mean, median, mode and standard deviation, random variables, discrete and continuous distributions: normal, Poisson, and binomial distributions. Tests of Significance, statistical power analysis, and sample size estimation. Regression and correlation analysis. Numerical Methods: Matrix inversion, nonlinear algebraic equations, iterative methods for solving differential equations, numerical integration.

Section 2: Electrical Circuits

Voltage and current sources: independent, dependent, ideal, and practical; v-i relationships of resistor, inductor, mutual inductor, and capacitor; transient analysis of RLC circuits with dc excitation. Kirchoff's laws, mesh and nodal analysis, superposition, Thevenin, Norton, maximum power transfer, and reciprocity theorems. Peak-, average- and rms values of ac quantities; apparent-, active- and reactive powers; phasor analysis, impedance, and admittance; series and parallel resonance, locus diagrams, realization of basic filters with R, L, and C elements.

Section 3: Signals and Systems

Continuous and Discrete Signal and Systems: Periodic, aperiodic, and impulse signals; Sampling theorem; Laplace, Fourier, and z-transforms; transfer function, the frequency response of first and second-order linear time-invariant systems, the impulse response of systems; convolution, correlation. Discrete-time system: impulse response, frequency response, pulse transfer function; DFT; basics of IIR and FIR filters.

Section 4: Analog and Digital Electronics

Characteristics and applications of a diode, Zener diode, BJT, and MOSFET; small-signal analysis of transistor circuits, feedback amplifiers. Characteristics of operational amplifiers; applications of opamps: difference amplifier, adder, subtractor, integrator, differentiator, instrumentation amplifier, buffer. Combinational logic circuits, minimization of Boolean functions. IC families: TTL and CMOS. Arithmetic circuits, comparators, Schmitt trigger, multi-vibrators, sequential circuits, flipflops, shift registers, timers, and counters; sample-and-hold circuit, multiplexer. Characteristics of ADC and DAC (resolution, quantization, significant bits, conversion/settling time); basics of number systems, microprocessor, and microcontroller: applications, memory, and input-output interfacing; elements of data acquisition systems.

Section 5: Measurements and Control Systems

SI units, systematic and random errors in measurement, expression of uncertainty - accuracy and precision index, propagation of errors. PMMC, MI, and dynamometer type instruments; dc potentiometer; bridges for R, L, and C, and Q-meter measurements. Basics of control engineering – modeling system: transfer function and state-space model, stability analysis: time domain and frequency domain analysis.

Section 6: Sensors and Bio-instrumentation

Types of Instruments: Resistive-, capacitive-, inductive-, piezoelectric-, Hall Effect sensors and associated signal conditioning circuits; Optical sources and detectors: LED, Photo-diode, p- analysis: time (APD), light dependent resistor and their characteristics; basics of magnetic sensing; Interferometer: applications in metrology; basics of fiber optic sensing. Basics of LASERs. Origin, nature, and types of Biosignals, Principles of sensing physiological parameters, types of transducers and their characteristics, Electrodes for bioelectric signals, Bioelectric signals, and their characteristics. Biopotential Amplifiers, Non-standards facts and their management, Electrical Isolation (optical and electrical) and Safety of Biomedical Instruments. Generation, Acquisition, and signal conditioning and analysis of biosignals: ECG, EMG, EEG, EOG, Blood ERG, PCG, GSR. Principles of measuring blood pressure, Core temperature, volume & flow in arteries, veins, and tissues – Lung volumes, respiration, and cardiac rate.

Section 7: Human Anatomy and Physiology

Essential elements of the human body-musculoskeletal system, respiratory system, circulatory system, excretory system, endocrine system, nervous system, digestive, nervous, immune, integumentary, and reproductive systems, Basics of cell and molecular biology.

Section 8: Biomechanics

Engineering Mechanics: Free-body diagrams and equilibrium; trusses and frames; virtual work; kinematics and dynamics of particles and rigid bodies in plane motion; impulse and momentum (linear and angular) and energy formulations, collisions. Hard Tissues: Definition of Stress and Strain; Deformation Mechanics. Bone structure & composition mechanical properties of bone, cortical and cancellous bones, viscoelastic properties, Maxwell & Voight models – anisotropy, Fatigue Analysis, Soft Tissues: Structure, functions, material properties and modeling of Soft Tissues: Cartilage, Tendon, Ligament, Muscle - Hodgkin-Huxley Model. Human Joints and Movements: Skeletal joints, forces, and stresses in human joints, types of joint, biomechanical analysis joints, parameterization and analysis in Gait, Biofluid

Mechanics: Flow properties of blood, Dynamics of fluid flow in the intact human cardiovascular system - modeling and experimental approaches, Pulse wave velocities in arteries, Measurement/Estimation of In-vivo elasticity of blood vessels.

Section 9: Medical Imaging Systems

Fundamental physics and Instrumentation of medical images in X-Ray, Ultrasound, CT, MRI, PET, FMRI, SPECT, and their characteristics.

Section 10: Biomaterials

Basic properties of biomaterials, biocompatibility, bioactivity, biodegradable materials, Fundamentals of implants and medical devices, drug delivery carriers, scaffolds for tissue engineering."

Appendix C: Funding for Biomedical Startups

India's biomedical industry is one of the fastest-growing sectors backed by India's rising income, health awareness, access to insurance, and increased lifestyle and stress-related diseases. Further, in India, doctor to patient ratio in the allopathy sector stands at 1:1596 (far lower than the 1:1400 WHO standard), and the country is ranked 145 among 195 countries on the healthcare index. This shows the enormous potential lying in front of health-tech startups in the 1.3 Bn-plus people economy.

Factors driving the growth of the medical devices sector

1. Market Factors – Growing population, ageing, income base, and associated disposable income, increasing socio-economic inclusion of rural and deprived in the mainstream economy, heightened manufacturing innovation to create customized products to meet the needs of all income segments, changing disease prevalence pattern (e.g., early onset of diabetes and heart diseases) and growing awareness among the middle class to focus on early detection and disease prevention.
2. Non-market Factors – Development of infrastructure, favorable regulations, FDI inflow, outsourcing of manufacturing and R&D activities to India, government initiatives to improve healthcare access through insurance schemes such as RSBY (Rashtriya Swasthya Bima Yojana), Aarogyasri, etc.

The lack of healthcare regulatory systems, harmonized standards, accreditation, legal requirements, proper guidance on quality and best practices, etc., are affecting the medical devices industry adversely[34].

34 RECOMMENDATIONS OF THE TASK FORCE ON THE MEDICAL DEVICES SECTOR IN INDIA -

MedTech Incubation Centers at AMTZ, Vizag

NITI Aayog supports MediValley Incubation Council (MVIC) under the Atal Innovation Mission. MediValley aims to enable a world-class technology start-up ecosystem by fostering entrepreneurship, which would provide the start-ups with necessary guidance, tech support, infrastructure, access to investors, networking, and other resources required for the start-up to survive and scale.

MedTech Incubator at IIT Madras

The MedTech Incubator (MTI) at IIT Madras is a joint initiative by the Indian Institute of Technology Madras (IITM) and the Department of Biotechnology (DBT), Government of India. The aim is to foster and stimulate MedTech designers and innovators, young entrepreneurs, and early-stage start-ups. The incubator also provides support and resources required for a MedTech start-up to survive. .

NHHID

The NHHID is a platform, supported by DST, for the integration of Clinicians, Scientists, Engineers, Technologists, Industrialists, and Businessmen, to accelerate the development of indigenous healthcare instrumentation. A Calibration center isbeing established.

BETiC

The Biomedical Engineering & Technology incubation Centre at IIT Bombay to scale up indigenous medical device innovation activities. They have 10 franchised BETiC centres in engineering and medical institutes across Maharashtra, which have developed a range of medical devices for diagnosis and treatment.

Medical Device Parks

As of now, there are more than 1000 manufacturing industries located in various parts of the country. Few MedTech Zones are created to reduce the import dependency by 40%. The first medical device park in India in Andhra Pradesh MedTech Zone Limited (AMTZ), it has taken India on the global map of high-end medical equipment production.

Center for Healthcare Entrepreneurship (CfHE) @ IIT Hyderabad

CfHE is a unique center, and a DST-approved Technology Business Incubator (est.

2015. Department of Pharmaceuticals Ministry of Chemicals and Fertilizers Government of India. 2015

[34a] https://gate.iitb.ac.in/syllabi.php

2016) that supports healthcare innovation through various programs and incubation activities. The center runs a one-year fellowship program that focuses on innovations in healthcare technologies and medical devices and the formation of start-ups in this domain. At CfHE, the fellows undergo rigorous clinical immersions and identify the hospital's unmet needs and follow a Biodesign thinking process to innovate, invent and implement their novel concepts. CfHE, in addition to offering fellowships, also incubates successful start-ups with seed grant support to translate innovative ideas from laboratory to clinic. The fellows get very broad exposure to healthcare innovation ranging from regulatory compliance, standards, IP, and business aspects of entrepreneurship, thus hand holding them towards creating successful start-ups. The center also undertakes incubation activities for cutting-edge deep tech startups in the area of healthcare. Startups trained at CfHE have built successful paths attracting over INR 20 crores in funding from various agencies, accelerator programs, and investors in the country. The Center works closely with BIRAC, DBT, and ICMR in translating products and services in healthcare in the ecosystem.

Other Agencies

- BMGF: http://gcgh.grandchallenges.org/
- Wellcome Trust: http://www.wellcome.ac.uk/funding/
- USAID: https://www.usaid.gov/
- USISTEF: http://www.usistef.org/
- Villgro Foundation: http://www.villgro.org/
- Lemelson Foundation: http://www.lemelson.org/
- Millennium Alliance: http://www.millenniumalliance.in/process_cycle.aspx
- Bharat Innovation Fund: http://bharatinnovations.fund/

Other Government Agencies

- DST: TSDP: http://www.dst.gov.in/technology-systems-development-programme-tsdp
- GITA: http://www.gita.org.in/
- DSIR-RDI: http://www.dsir.gov.in/12plan/bird-crf/rdi.htm
- PRISM: http://www.dsir.gov.in/12plan/prism/prism.htm
- Csir-NMITLI: http://www.csir.res.in/external/heads/collaborations/nmitli.htm
- DSIR Programmes: http://www.dsir.gov.in/aboutus/intro.htm
- SIDBI Startupmitra: https://www.sidbistartupmitra.in/
- List of SEBI registered Funds:
- http://startupindia.gov.in/uploads/pdf/List_of_SEBI_Registered_Funds.pdf

Angel Funding & Investors

- Indian Angel Network (IAN)- https://www.indianangelnetwork.com/
- Mumbai Angels -http://www.mumbaiangels.com/angel_investing.php
- Biotech Angels -http://ableindia.in/pdf/biotechangels.pdf

- Lead Angels, Pitch India, TiE - http://leadangels.in/
- Hyderabad Angels-http://www.hyderabadangels.in/
- Kolkata Angels- http://calcutta-angels.com/
- HNI (High Networth Individuals)
- BIRAC: SBIRI, BIPP, CRS (http://www.birac.nic.in/#)

Accelerators

- http://healthstart.co.in/accelerator-program.html
- http://www.evaccel.com/
- http://axilor.com/
- https://www.microsoftventures.com/programs
- Emergency & healthcare devices: http://innaccel.com/
- Others listed at http://startupindia.gov.in/funds.php

Venture Capital Fundings

Series A

- Sequoia, Accel, Greylock, GVFL Ltd., Aarin Capital, Artiman, Ankur Capital, Calamaran, Lightbox, Matrix, Mayfield Fund Kitven, Reliance Life sciences, MPM Bioventure IV
- Investors help startups to get into the next level by expanding market reach

Series B

- Sequoia, Venture East, Warburg, Canaan, Bain Capital, Helion, Blume, Fidelity
- Scale-up of a company

Series C

- Investment banks
- Private equity: Kotak Private Equity, Softbank, TIGER Capital

Approvals for Clinical and Field trial

- Approval through DCGI: https://cdscoonline.gov.in/
- Register for clinical trials: http://ctri.nic.in/Clinicaltrials/login.php
- Clinical Trials for new drugs and cosmetics:: http://octams.gov.in.
- Regulatory Policies http://cdsco.nic.in/html/downloads.html
- GMP form: http://cdsco.nic.in/html/GMP/ScheduleM%28GMP%29.pdf
- Indian Pharmaceutical association:
- http://www.ipapharma.org/regulations.aspx

Appendix D: Biomaterials Research in India

The biomaterials market is one of the fastest-growing sectors in the healthcare industry. Factors such as increased funding and grants by government bodies for the development of novel biomaterials, increasing incidence of cardiovascular diseases (lifestyle diseases) and cancer, the rising demand for medical implants, and increasing access to health insurance are helping the growth of the biomaterials market.

It has been predicted that China, India, and Japan become the major emerging markets for biomaterials and medical device products. The current market size for the biomaterials and medical devices industry in India is estimated to be $ 5.2 billion, accounting for about 4-5% of the total healthcare industry market. This is expected to be a 50 billion industry by 2025 (1, 2). This emphasizes the potential and needs for research and development in biomaterials, tissue engineering, drug delivery, and medical devices, and related education in this interdisciplinary research area in India.

The earliest developments in biomaterials research date back to 1984, when the technology for blood bags made from polyvinyl chloride (PVC) was developed by Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST). The commercial production of blood bags started in 1987, which eventually replaced glass bottles to store blood. There were many challenges in the initial stages, from developing blood-compatible polyvinyl chloride sheets with minimal phthalate leaching to the final sterilization procedures.

The indigenous TTK Chitra heart valves which followed had their first human implantation in 1990 and multicentre trials starting from 1992. The TTK Chitra heart valve has good hemodynamics with no structural failure and acceptable thromboembolic levels. This valve was cost-effective, readily available, and user-friendly, which became the choice in many centers dealing with rheumatic heart diseases.

With other devices like membrane oxygenators, hydrocephalus shunt, vascular graft, hydroxyapatite-based dental and bone grafts, etc., SCTIMST has played a significant role in the emergence of biomaterials science engineering in India. Since then, numerous other government and other private institutions, including the Indian Institutes of Technology, have devotedly promoted biomedical engineering and technology in this country through research, innovative training programs, and product development (Table 1).

Present-day development on biomaterials mainly focuses on tissue engineering and nanotechnology-enabled drug delivery, including 3D bioprinting and theranostics. The years of study on the interaction of biomaterials with biological systems opened up the scope of growing cells in biomaterial scaffolds. These findings and the developments in biotechnology and biomechanics led to the idea of re-growing defective tissues. That created a new area of 'Tissue Engineering' and 'Regenerative Medicine' for enabling the repair regeneration of tissues. This eventually led to a new technique of 3D bio-printing enabling printing of scaffolds incorporating cells and growth factors. Shortly, surgeons may print a human organ on demand.

Other medical devices under development are Para-corporeal left ventricular assist device (LVAD), centrifugal blood pumps, an aortic stent for endovascular treatment of thoracic aortic aneurysm, etc. Deep brain stimulator systems for patients suffering from various movement disorders and implantable cardioverter defibrillators for defibrillation and pacing of the heart are other device development areas. Injectable hydrogel development for the repair of cartilage injury is beneficial in the traumatic or degenerative injury of the cartilage. Scaffolds made from synthetic and natural bioceramics, polymers, and their composites demonstrated significant osteoconductive properties. These matrices also demonstrated osteogenic differentiation capacities helping bone regeneration in bone tissue engineering. Various groups in India demonstrated the effectiveness of growth factors, other polymeric biocomposites incorporating alumina and zirconia in increasing the scaffold bulk toughness, bioactivity, and cellular adhesion in developing scaffolds for hard tissue applications.

Improving the transfection efficiency utilizing novel polymers in non-viral gene delivery; stimulated delivery of growth-promoting agents to modulate cell differentiation in tissue-engineered scaffolds; targeting anticancer drugs to increase specificity and reduced toxicity in anticancer therapy are some of the latest research areas in drug delivery. Theranostics is a relatively new drug delivery approach where both therapeutic and diagnostic capabilities are combined in one dose and a promising approach towards personalized medicine. Guided drug delivery is another investigation approach where the biodistribution and target site accumulation of drugs can be visualized and quantified to assess their efficacy non-invasively.

The outcome of biomaterials research has been instrumental in improving patient compliance and quality of life. The translation of research outcomes to advanced medical technologies is crucial to realize newer biomedical products. The knowledge base derived from the emerging areas of tissue engineering, nanotechnology, biosensing, diagnostics, etc., can open new avenues that can potentially revolutionize the area of biomaterials science and engineering in India.

Trained manpower/Human resource development is very much needed in India to improve quality R&D. Industry institute partnership needs encouragement;

Interdisciplinary research with clinicians is much needed; Value of patents, maintaining an excellent quality system and technology transfer needs to be encouraged, and the Techoprove facilities and startups need emphasis with many research parks. We also need to look into the ethical guidelines and protocols with changing scenarios of emerging tissue engineering and regenerative technologies and think of futuristic cell banks with patient-specific organ development centers with stringent ethical guidelines.

Comprehensive knowledge-based growth of Biomaterials Science and Engineering is necessary for developing excellent quality and internationally competitive products. Selection of appropriate products and collaboration based on complementary facilities and infrastructure are essential ingredients. That is where excellent comprehensive interdisciplinary M.Tech and Ph.D. programmes need to be established in the country.

Table 1: Different groups working on Biomaterials Science & Engineering in India

	Research Group	Research Group
1	CV Muraleedharan, GS Bhuvaneshwar, AV Ramani, MS Valiathan, SCTIMST, Thiruvananthapuram	Tilting disc mechanical heart valve. TTK Chitra valves
2	Chandra P. Sharma, SCTIMST, Thiruvananthapuram	Surface Modification, Biocompatibility, Oral Insulin Delivery, Wound Healing Devices, Theranostics
3	SN Pal, V. Kalliyana Krishnan, SCTIMST, Thiruvananthapuram	Blood Bag, light-curing dental cement
4	SK Guha, IIT Delhi & AIIMS Delhi	Rehabilitation engineering, non-hormonal based injectable male contraceptive, bioengineering in reproductive medicine
5	Subrata Saha, Jadavpur University	Bioceramic
6	K Panduranga Rao, CLRI	Natural apatite scaffold, drug deliver
7	S Basu, IIT Bombay	Blood/biocompatibility of materials
8	CV Muraleedharan, SCTIMST, Thiruvananthapuram	Deep brain stimulator, Cardioverter defibrillator
9	DS Nagesh, V Vinodkumar, SCTIMST, Thiruvananthapuram	Blood Pumps, LVAD

10	Bikramjit Basu, IISc Bangalore	Multifunctional toughened nanostructured ceramics, modulation of cell functionality by electrical/magnetic stimulation
11	TS Sampath Kumar, IIT Madras	Bioceramic implants, multimodal drug delivery and imaging, injectable bone and dental cement, biofunctionalized metallic implants
12	Harikrishna Varma, SCTIMST Thiruvananthapuram	Hydroxyapatite based bioceramic implants
13	Rinti Banerjee, IIT Bombay	Nanostructured biomaterials, nano-drug delivery, pulmonary surfactants
14	Biman Mandal, IIT	Tissue engineering, 3D disease tissue models, bioreactors, and drug deliver
15	Manzoor Koyakuty, K. Jayakumar, AMRITA Kochi	Drug delivery, Image-guided therapy, Composite scaffolds, bone tissue engineering,
16	Dhirendra S. Katti, IIT Kanpur	Bionanotechnology, tissue engineering, drug delivery
17	Veena Koul, IIT Delhi	Drug delivery, soft tissue regeneration, nanohybrid particles targeting cancer cell
18	Santanu Dhara, IIT Kharagpur	Cell-material interaction, customized scaffolds, medical textile, skin, bone, and cartilage tissue engineering
19	Sourabh Ghosh, IIT Delhi	Textile technology, Tissue Engineering
20	Bhuvanesh Gupta, IIT Delhi	Polymer functionalization, transdermal drug delivery, wound dressing, surgical sutures
21	Jayesh R. Bellare, IIT Bombay	Bone-scaffolds, nanobiocomposites coatings, hollow fibre membranes
22	SC Kundu, IIT Kharagpur	Silk fibroin for tissue regeneration and drug delivery
23	Kantesh Balani, IIT Kanpur	Ceramic polymer biocomposites, dental implants
24	Prabha D Nair, SCTIMST, Thiruvananthapuram	Cartilage tissue engineering

25	S. Kar, IIT Bombay	Cell signaling, diagnostic measure for different life-threatening diseases

Appendix E: Societies of BME in India

Networking of scientists and engineers is vital for personal and professional development. Professional societies sponsor conferences, publish journals, and serve as reviewers or editors. They set professional and educational standards and provide job and career services for their members. While other countries have many professional bodies for Biomedical Engineering, it is unfortunate that India does not have any active BME societies. There are a few, but mostly defunct.

Biomedical Society of India (BMESI)

The Biomedical Engineering Society of India (BMESI) is an All India non-profit making professional learned body. Currently, the Manipal Institute of Technology acts as the headquarters. BMESI came into being in 1994 to integrate engineering and medicine to directly impact the healthcare industries with collaborative projects and events, closely working with a team of doctors and other healthcare professionals.

Indian Society of Biomechanics

It is more than two decades that the Indian Society of Biomechanics was conceived and established in IIT Delhi at the Center of Biomedical Engineering, especially with the active participation of Prof. K.B.Sahay, Prof. R.K.Saxena, Prof. S.K.Guha and Prof. Sneh Anand, all from IIT Delhi and Prof. S.Pal of Jadavpur University, and many others. Prof. D.K.Sinha, the Dean of Faculty of Science, Jadavpur University, was nominated as the president of the society. It was inaugurated at the end of the first national seminar on biomechanics at IIT Delhi, and subsequently, Prof. P.K.Dave, Director of AIIMS, took over as the president of the society.

Indian Biomedical Skill Council (IBSC)

Andhra Pradesh MedTech Zone (AMTZ), Association of Indian Medical Manufacturers of Medical Devices (AiMeD), and National Accreditation Board for Certification Bodies (NABCB) under the Quality Council of India (QCI) have jointly established "Indian Biomedical Skill Council (IBSC)" to provide certification system for Biomedical Engineers in the country who serve as the backbone of the healthcare services.

IBSC aims at strengthening the Biomedical Skill Sector in the country and, with this objective, develop job roles and approved by National Skill Development Agency (NSDA) and aligned with the National Skill Qualification Framework (NSQF) under the Ministry of Skill Development & Entrepreneurship (MSDE).

IBSC also signed an MoU with the Association for the Advancement of Medical Instrumentation (AAMI) USA for International recognition & equivalence of IBSC Certified professionals. This MoU benefits the IBSC certified candidates will have equal opportunities to practice the biomedical profession globally.

Society of Biomedical Technology

The Society for Biomedical Technology (SBMT) is an interministerial initiative of the Government of India established to promote healthcare by providing indigenous solutions in medical equipment and devices.

The Society for Biomedical Technology was established under the Department of Defence Research and Development DRDO) in collaboration with the Department of Science and Technology (DST), Ministry of Social Justice and Empowerment, and Ministry of Health & Family Welfare. The activities of the Society are carried out by the Laboratories of Defence Research and Development Organisation and a few other well-known Academic Institutions and Medical Centres.

The Society was officially launched on 27 June 1993 at Nizam's Institute of Medical Sciences (NIMS), Hyderabad, by Dr. P Rama Rao, the then Secretary, DST, in the presence of His Excellency Dr. APJ Abdul Kalam, Former President of India and the then Secretary, DRDO & also Scientific Adviser to Raksha Mantri. The Society was registered at Bangalore under the Registrar of Societies, Karnataka, on 1st October 1993, and the registered office of SBMT is located at Defence Bioengineering and Electromedical Laboratory (DEBEL), Bangalore. The Director, DEBEL functions as the Chief Executive of the Society.

Indian Academy of Biomedical Sciences (IABS)

Indian Academy of Biomedical Sciences (Regd.) has been established in order to promote research in the field of translational sciences. The academy has been registered under the Societies Act 1860 of the Government of India, with Registration No. 2826-2011-2012.

The academy's main aim is to disseminate knowledge and promote academic excellence in Biomedical Sciences. The academy was formed with the vision, keen interest, and efforts of several scientists from India and abroad.

Initially, the initiative to form the Academy was taken by Prof. Hari S. Sharma, Department of Pathology, UV University, Amsterdam, Netherlands. Prof. Sharma discussed the idea with Prof. Abbas Ali Mahdi during one of his visits to his laboratory at King George's Medical University, Lucknow, India. After that, Prof. Mahdi got the Academy registered at Lucknow on 7th February 2012.

Dr. M. Manivannan is a professor of Biomedical Engineering in IIT Madras, Department of Applied Mechanics. He received post-doctoral training at the Massachusetts Institute of Technology (MIT) in Cambridge. He was a visiting scientist at the Massachusetts General Hospital (MGH) of Harvard Medical School (HMS) in Boston, and a visiting faculty in the Christian Medical College (CMC) Vellore. Before MIT and Harvard, he received another post-doctoral training at the National Institute of Standards and Technology (NIST) Maryland. In 2005 Dr. Manivannan set up the first Touchlab in India at IIT Madras, which is still unique in India. He has recently set up Experiential Technology Innovation Center (XTIC) which is the first multidisciplinary center for VR/AR/MR and Haptics in India.

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