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REVIEW ARTICLE

Biomedical Engineering Profession – An Overview and Global Comparison of Staffing Criteria and Workforce

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ABSTRACT

Introduction: Biomedical Engineering is a specialized profession that incorporates engineering, science, technology, and medicine competence and responsibilities. A biomedical engineer who works at hospital and manages the biomedical engineering department by integrating all the health care technologies for patient safety is called a clinical engineer.

Methodology: Rapid literature on the workforce as well as staffing criterion has been done by searching in PubMed, google scholar and relevant websites.

Results: Variations in the staffing criteria exist across all the world. There are multiple staffing criterions put forward by various health system agencies. However, a standardised staffing criterion is lacking in many countries. The conventional staffing pattern developed primarily on the basis of number of patients needs to be modified by incorporating multiple components such as the nature of care delivery, number of biomedical devices used, average number of maintenance work orders received etc. The procurement and maintenance of biomedical devices are often get disrupted in developing countries due to inadequate staffing. Low-income countries depend on donations for procurement of medical devices, however most of these devices will stop working within a period of 5 years due to lack of maintenance.

Conclusion: Developing an appropriate job description specific to the county and adopting a standardised staffing pattern could contribute immensely to the medical workforce as well as improving the quality of medical care.

Manuscript Highlights

This paper provides an overview of considerations used to develop staffing criteria for biomedical engineers across the globe. The paper also does a multicounty comparison on biomedical workforce published by the World Health Organisation in order to determine the various factors to be considered for developing a staffing criterion. High income countries like Australia, Canada and USA follows standards according to their requirements whereas the LMICs doesn't follows a framed criterion. The paper discusses various models available in place which are used by various health administrative agencies to consider developing and regulating the staffing standards of biomedical engineers in their respective regions. The paper examines the health regulations considering the biomedical engineer staffing criterions developed by regulatory and administrative agencies from different countries. Based on all these analyses, recommendations are made on criterions to be considered for developing staffing pattern and implementing regulatory body for biomedical engineering profession.

Keywords: Staffing, clinical engineer, Low-middle-income countries

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INTRODUCTION

Biomedical Engineering is a specialized profession that incorporates engineering, science, technology, and medicine competence and responsibilities.[1] As per the American College of Clinical Engineers (ACCE), the term clinical engineering and Biomedical Engineering are synonymously used.[2] Preventive maintenance as well as repair are the two major functions of biomedical engineering department. Other tasks include but not limited to the incoming inspection and installation, prepurchase evaluations, purchase request review, equipment replacement and upgrade planning and implementation, coordinating vendor service, hazard/recall monitoring and notification, daily inspection, breakdown log, equipment incident review, ensuring regulatory compliance, committee participation, and user/maintainer training and coordination. According to International Federation of Medical and Biological Engineers (IFMBE) Medical and biological engineering profession integrates physical, mathematical and life sciences with engineering principles for the study of biology, medicine and health systems and for the application of technology to improving health and quality of life. It creates knowledge from the molecular to organ systems levels, develops materials, devices, systems, information approaches, technology management, and methods for assessment and evaluation of technology, for the prevention, diagnosis, and treatment of disease, for health care delivery and for patient care and rehabilitation.[3] The standards and criterions for setting up biomedical engineering departments and clinical engineering standards are better established in high income countries in comparison to low- and middle-income counterparts.[4]

The International Labour Organization (ILO) manages the International Standard Classification of Occupations (ISCO), which organizes the tasks and duties of jobs, with the objective of having international reporting and statistical data of occupations and serves to enhance national and regional classification of occupations. The current system, ISCO-08, classifies BME professionals as a part of Unit Group 2149 Engineering Professionals not Elsewhere Classified.[5]

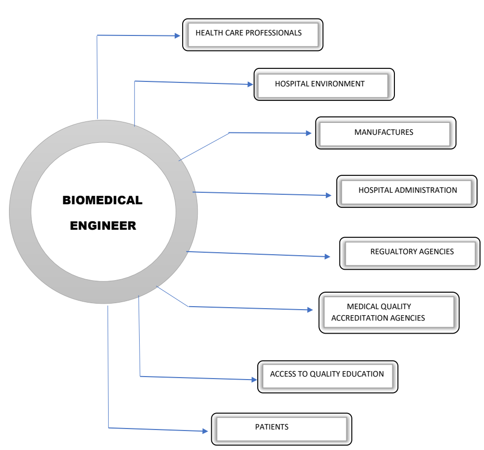

Figure 1: Clinical Engineer and the range of interactions with other professional domains[6]

Biomedical engineering" professionals are considered to be an integral part of the health workforce alongside those occupations classified in Sub-major Group 22: Health Professionals. It is important to recognize that although ISCO-08 has "noted" biomedical engineers as an integral part of the health workforce Figure 1, the profession has not yet been independently re-classified as a specialized type of engineering.[5]

Problem Statement

There are no standardised staffing criteria recommended for biomedical engineers (BMEs)[6]. Integrated health management consortiums like Kaiser Permanente devices certain strategies to improve the staffing criteria for BMEs.[7] With an exception to certain academic medical institutions like The

Ottava General Hospital, most of the institutions around the globe fails to define an appropriate staffing criterion for the biomedical engineers.[8] Medical device technology is developing faster and innovations in the field of bio-medical research has got direct result in terms of patient wellbeing. Solar powered oxygen concentrators and ventilators developed to manage secondary and tertiary care Covid 19 patients during the pandemic period is one of the examples.[9] Translating the innovations happening in the research organisations and industries into the medical practices are still getting restricted due to the lack of adequate support system at the hospital level.[10]

Aim of the Review

The aim of this review is to determine the parameters used across the globe to set staffing criteria for biomedical / clinical engineers. The review also does a comparison of global workforce of biomedical engineers.

METHODOLOGY

A rapid literature review has been done to evaluate the criteria needs to be considered for developing staffing criterion for Bio Medical Engineers by doing a literature. We have searched in PubMed for the terms of 'Biomedical Engineer / clinical engineer Staffing Criteria' 'staffing model for biomedical engineer' 'biomedical engineering workforce' We have also conducted literature search among the wider resources surrounding staffing criteria mentioned in World Health Organisations website for global workforce comparison, to identify published biomedical articles mentioning staffing criteria Table 1. Concurrently we have searched in ministry of health websites of various countries, Non-governmental Organisations, International Labour Organisation from year 1975 to 2022. Two reviewers independently screened literature search and extracted papers. A descriptive analysis was conducted.

Staffing

Staffing in simple term translates the number of FTEs needed to carry out a clinical engineering intervention. It differs between hospitals depending upon various factors such as the program's depth and breadth. It is also influenced by other

Table 1: Classification of research papers

Sl no	*Author*	*Year*	*Country*	*Title*	*Recommendations*
1	Antonio Miguel Cruz & Mayra R. Guarín	2016	Nordic countries, North America, Southern Europe Western Europe, Latin America and Australia	Determinants in the number of staff in hospitals' maintenance departments: a multivariate regression analysis approach	There are almost 14 biomedical technicians (BMETs) per clinical engineer and one FTE per 1083.72 devices. The total number of devices and the total technology management hours devoted to these devices positively affects the number of FTEs in a CED, and. hospital complexity, patient discharges affect inversely.
2	WHO medical device technical series: to ensure improved access, quality and use of medical devices	2017	All countries	Human resources for medical devices The role of biomedical engineers	Provides an overview of the global biomedical engineering workforce
3	Mohamed Ibrahim Waly	2020	Saudi Arabia	Evaluation of Clinical Engineering Department Services in Riyadh City Hospitals	The hospital size affects the technical and training skills of CED staff as well as the established maintenance management
4	Joseph Bronzino	2005	USA	Introduction to Biomedical Engineering	The discipline of biomedical engineering integrates medicine and engineering. Evolving medical technologies and its role in improving the health and wellness
5	Matthew D McHugh et. al	2016	USA	Achieving Kaiser Permanente quality	Consideration of magnet designation is a proven cost-effectiveness strategy to achieve the Kaiser Permanente quality
6	Payal Mandot et.al	2020	Canada	Biomedical Engineering Department Staff Analysis: The Ottawa Hospital Productivity Review	Service contracts should be analysed routinely. The technological needs of the biomedical department shall be considered to sort the day-to-day problems. analysis by site to obtain the number of devices per technologist and a cellular analysis of workload per technologist will help in achieving a balance and reducing waste to achieve greater efficiency
7	Jonathan Gaev	2010	USA	Successful measures Benchmarking clinical engineering performance	Shall prioritise measures of inspection, repair and preventive maintenance as these activities together constitute more than 80% of the clinical engineering department activities
8	Antonio Miguel Cruz & Mayra R. Guaríneld	2016	Canada, USA	Determinants in the number of staff in hospitals' maintenance departments: a multivariate regression analysis approach	The total number of devices and the total number of technology management hours have a favourable impact on the number of FTEs in a CED, but hospital complexity, as determined by patient discharges from healthcare organisations, has an adverse impact. The overall amount of technology management hours spent to medical devices was the most significant factor that affected the number of FTEs in CEDs.
9	Binseng Wang et.al.	2012	USA	Clinical Engineering Productivity and Staffing Revisited How Should It Be Measured and Used?	Staffing and productivity shall alone not be the only factors used for determining the cost effectiveness of clinical engineering departments

10	Ted Cohen	2012	USA	Staffing Metrics: A Case Study	Developing metrics for quantifying the staffing needs with respect to workload will ease the budget allocation
11	Md. Anwar Hossain et.al	2020	Bangladesh	Mathematical modelling of clinical engineering approach to evaluate the quality of patient care	Integrating clinical engineering approach to patient care delivery system will enable the safety and timely functionality of medical devices
12	C. Lamberti et.al	1997	Italy	A new model to estimate the appropriate staff for a clinical engineering department	Determining appropriate size of the clinical engineering department will lead to improvements in health care services. Hence appropriate determination of engineering staff, technicians and administrative staffs intended for managing the eqipments must be present.
13	Isobel H Marks et.al	2019	United Kingdom	Medical equipment donation in low-resource settings: a review of the literature and guidelines for surgery and anaesthesia in low-income and middle-income countries	Ensuring appropriate functionality and long-term sustainability of donated biomedical devices in LMICs could only be possible through appropriate user training to biomedical engineers. Equitable partnership is between donors and recipients are integral to check inappropriate donations.

factors like experience of the staffs, overall inventory mix, inclusion as well as maintenance criteria, data on equipment under service contract, the purchasing procedures followed for services as well as parts. Some of the commonly used methods for estimating a staffing criterion include, quantity of beds per FTE, total number of parts of equipment per FTE, the total cost of acquisitions per FTE and FTE calculator. Apart from the FTE calculator method, all others follow simple method which includes single criterion. The FTE calculator is considered as the most reliable and accurate method for determining FTE. This strategy necessitates precise data on the time invested for conducting different clinical engineering procedures. Time invested for scheduled activities such as Preventive Maintenance may be precisely foreseen. However, the time spent on unplanned tasks (for example, repair as well as arriving inspection for the recent instrument) can't be precisely calculated. Based on past data, repair time can be approximated. The amount of time invested on routine inspections for new equipment differs according to the size of the new equipment acquired by the health care institution. Also, troubleshooting & repair together are called corrective maintenance. Furthermore, the amount of time spent on additional operations such as post purchase assessments, purchase request cross check, equipment upgradation as well as replacment, and execution differs by institution.[11]

All these criterions used for estimating staffing are obtained from national employment studies, national and international studies conducted to determine the CED department features, mathematical models as well as statistical regression analysis.[12]

Estimating the Staffing Criteria

A multitude of factors determines the criteria to design a staffing criterion for biomedical engineers. The major determinants include, type and location of health care institution, availability of resources as well as the budget. There are two most commonly proposed criterions for biomedical engineer staffing pattern. At least one biomedical engineering technician per 1000 pieces of medical equipment's or 2.6 fulltime employees per 100 beds. Though there were many bench marking studies conducted during 1980s and 90s, little attention has been received later. The ARAMARK developed some critical parameters that could better predict the staffing criteria by taking into account.[13]

- The total number of beds in operation
- Patient discharges adjusted in total
- Patient days adjusted in total
- Overall operating expense for hospital
- Total number of parts of medical equipment
- Overall acquisition cost of medical equipment
- Total scheduled and unscheduled number of maintenance work orders.

The AAMI (Association for the Advancement of Medical Instrumentation) devised benchmarking solution for developing staffing metrics. The major components considered include acquisition value of equipment, full-time equivalent (FTE) counts, device counts per FTE, derived hourly cost, cost of service ratio (COSR) Table 2.[14]

Dummert Matt recommends that one size fits all formula will not be applicable to every facility. The biomedical engineering environment is constantly changing. Hence, a fixed staffing model might not be able to provide required full time employ equivalents to function the biomedical engineering department.[15]

RESULTS

Global Scenario

There is a direct corelation exists between presence of a Clinical Engineering department and quality of Patient Care (QPC). Taking this into account, many countries especially high-income countries like Japan established clinical engineering departments with excess number of employees (BMETs & CEs) in their hospitals. This approach however is costly and countries such as South Africa, Jordan, etc. established CEDs with inadequate number of employees. On the other hand, Indonesia, Nepal, Bhutan, Bangladesh etc. established patient care services without having CEDs in their medical institutions.[16] In many of the countries with inadequate CEDs, one major challenge is up to 75% of the equipment's available will be in non-operable condition either due to lack of adequate infrastructure or due to no proper installation. According to Meyer-Hartwig and Bleifeld, in Germany there must be at least one clinical engineer per 300 beds. In the case of United States of America, Pacela et al estimates that one Biomedical Engineering Technician per every 136 and 402 beds that is the ration of BMET to CE is 3:1. Frize et. al [16] proposed an amendment to the criteria by incorporating the factor of hospital as well as inventory size. As per their criteria, they should be one CE and 3 BMET shall be there per 400 equipment. Another major contribution to the staffing criteria came from Glouhova et.al.[17] After incorporating data from western and southern Europe, Australia and Latin America, they proposed the staffing criteria varies according to the socio-economic status of the countries. The number of staff got decreased from high income countries to low-income countries. C. Lamberti et.al.[16] states that the rise in number of clinical engineers especially in US could be corelated to the increase in the number of laws and regulations set by the health department. There has been more than three times of increase happened in the total recruitment in CE staffs in the US in the previous decades. Following this, there is an annual increase of 11.5% and 8.2% rates in the recruitment of CE and BMET respectively. The Irnich Model primarily used in Germany determines the number of technicians necessary for managing the clinical infrastructure once the final number of technicians are able to identify, the acceptable number of clinical engineers will be one per 5/6 of BMETs.[16] Another model called the Frize Model, which is commonly used in USA, considers re-purchasing value of the instrument to be an important criterion to estimate the optimal number of staffs. As per Frize, for every 400 pieces of equipment worth of 1-1.5 million worth of repurchasing value one technician is required and 1 engineer per 3-5 technicians. Another model proposed to categorise the CEDs into 3 levels in which the 1st level carries out the activities for managing the equipment only, the 2nd level carryout the safety inspection as well as first inspection and the 3rd level carries out all the activities including trainings.[16]

DISCUSSION

The major benefits of having biomedical engineers in the biomedical department are many, however the most Common are;

- Efficient specification of equipment – A BME could be the aid the health care institution in the purchase of the most efficient device in terms of compatibility to the clinical setting
- Timely and cost-effective maintenance and repair – This will limit the equipment failure incidents to a great extent and will ensure non-disruption of the clinical procedures.
- Equipment management – Timely replacement, servicing as well as maintenance is of prime importance. This will not only ensure proper maintenance but effective equipment usage management.
- Calibration and validation – are extensively important to achieve highest standards in the biomedical equipment
- Research, development and translation – To bring together specialist skills in various domains of engineering disciplines and to couple it with medical practice knowledge to bring innovations in the arena.

Scenario in India

The National Health Mission of India in its Biomedical equipment management and maintenance program suggests for region wise staffing criteria for biomedical engineers Table 3. However, it doesn't take into account many of the criteria which are necessary to be considered such as the number of instruments available in a hospital. The program encourages to outsource the maintenance and service of biomedical devices by outsourcing to third part agencies. This might not always be cost effective as there are no detailing about the quality and cost of third-party service to be considered.[17]

Though Facilities Management Safety (FMS 4 & 5) under Chapter 8 of the standards and objectives of the NABH accreditation standards for hospitals ensures the organisation has a programme for managing medical equipment as well as a programme for the facilities, engineering support services, and utilities system, this often been practiced only on paper in many institutions.[18]

In India, there are 0.12 hospitals having a biomedical department/unit/service for every 100,000 people, based on the WHO's Global Survey on academic and professional profiles of biomedical engineers and technicians.[21] India is one of the 8 countries with WHO medical device unit collaborating centres along with, Canada, Brazil, Colombia, China Mexico as well as United States Table 4. Major biomedical companies which focusses currently on creating equipment that is suitable for regional requirements and situations, and that works better and is more sustainable in light of regional requirements. These

Table 2: Criteria considered for developing staffing pattern for biomedical engineers[8]

Health Care Institution	
1	Healthcare organisations discharges
2	Total devices
3	Total acquisition cost of devices
4	Total quantity of imaging as well as therapeutic radiology equipment
5	Imaging and therapeutic radiology procurement cost
6	The ratio of imaging and therapeutic radiology eqipments in total with their procurement cost
7	Total quantity of the laboratory eqipments
8	Procurement cost of laboratory equipment
9	Total quantity of laboratory equipment procurement cost ratio
10	Total quantity of general biomedical eqipments
11	Procurement cost of general biomedical eqipments
12	Total quantity of general biomedical equipment procurement cost ratio
13	External maintenance contracts expenses/year
14	In-house maintenance cost/year
15	External maintenance cost to total maintenance cost ratio
16	Cost of Service Ratio (COSR)
17	Percentage of hospitals with CED based on their in-house model
Clinical Engineering Department (CED) details	
1	CED total space (square feet)
2	Total FTEs
3	Total CED expenses
4	Total Technology management (hours)
Workload details	
1	Travel time (hours)
2	In-house maintenance (hours)
3	Training received (hours)
4	Product alerts / recalls (hours)
5	Incident investigation (hours)
6	Pre-procurement technology evaluation and strategic planning (in hours)
7	Teaching (hours)
8	Special tasks, IT projects (hours)
9	Number of devices per FTE (for BMET and clinical engineer)

devices are often found to perform better than that of the ones who are imported from other countries. This suggests for more investment and research in the development of instruments indigenously.

The distribution of biomedical engineers in India is Low with only 1500 estimated BMEs working per 16000 health care facilities.

Interventions

Most health care systems across the world are structured around the primary contact health care professionals or vertically expert professionals like clinical health care workers, administrative staffs, medical physicist etc. However, the horizonal professionals is equally necessary to ensure the uninterrupted as well as efficient clinical functioning of any health care facility. The lack of knowledge and awareness regarding the health regulators as well as policy makers are delaying the engagement of biomedical engineers into the clinical forefront.[19]

Global Clinical Engineering Alliance (GCEA)

GCEA is the dedicated international organisation working for the improvement of clinical engineering profession for improving the health care outcomes. Major objectives of GCEA are to develop a platform to consult, plan, practice and to create awareness on technical guidelines, as well as regulations related to health technology. GCEA was created to address the common international challenges existing. The alliance organised “International Clinical Engineering and Health Technology Management Congress” (ICEHTM) on 2015 in China. This facilitated to develop a global platform for showcasing the global best practices in clinical engineering, promotion of innovative technologies, and to formulate cross discipline engagements. [20]

Table 3: Biomedical Engineering Departmental Staffing criteria in various Countries[3-5,10,15,18]

Country	Organization/Region	Staffing Criteria of BME (Bio Medical Engineering) Department
India[(15)]	Ministry of Health and Family Welfare, National Health Mission, National Health System Resource Centre (NHSRC)	State equipment cell – 3, (certified medical equipment technicians – 5)
		Divisional BME – 3 per division, (certified medical equipment technicians - 2)
		District equipment cell – 3 per district, (certified medical equipment technicians – 5)
		CHC (Community Health Centre)- certified medical equipment technicians – 1 per CHC
		PHC (Primary Health Care) - certified medical equipment technicians – 1 per PHC
Canada[(10)]	The Ottawa Hospital (TOH)	"0.5 FTE Director, 1 Acting Manager, 1 Biomedical Engineer, 1 CMMS administrator and 31 Technologists out of which 8 are Diagnostic Imaging Technologists"
	Canadian Paediatric Hospital	"1 Director, 2 Managers, 4 Clinical Engineers, 1 Clinical Engineering Intern and 26 Technologists"
	Canadian East coast Medical College	"1 Director, 5 managers, 5 clinical engineers, 5 team leaders, 5 senior technologists and 5 technologists."
	Canadian East coast Medical College	"1 Executive Director, 3 directors, 6 Admin staff, 6 Biomedical Engineers, and 18 supervisors, with the rest being senior technologists, consultants, and technologists"
USA[(3–5)]	ARAMARK Healthcare Technologies	"2.5 FTEs (Full Time Employers) per 100 operating beds and 0.5% of hospital staff and about 5 FTE per 100 adjusted discharges or 1 FTE per 600 devices and 1 FTE per $9 million (USD) in assets"
Bhutan[(18)]	Department of Medical Services Ministry of Health, (MoH), Thimphu	"Biomedical engineering services at Districts hospitals - Assistant Biomedical Engineer (1) with 4 numbers of assistants including Junior engineer and support staff"
		"Biomedical Engineering services at the Regional Referral Hospital - Executive Biomedical Engineer (1) with 8 numbers of assistants including Dy. Executive Biomedical Engineer, Biomedical engineers, Assistant Biomedical Engineers, Junior Biomedical Engineer 26 and support staff (3) (Computer operator – 1, Painter – 1, Store keeper – 1) Total = 12"
		"Biomedical engineering services at the National Referral Hospital - Technical Director (Specialist) with 17 numbers of assistants including Chief Biomedical Engineer, Executive Biomedical Engineer, Dy. Executive Biomedical Engineer, Biomedical Engineer, Assistant Biomedical Engineer, Junior Biomedical Engineer and support staff (3) (Computer operator – 1, VTI Painter – 1, Store keeper – 1) Total = 20"

Table 4: Biomedical Engineer Density Across the Globe on the Basis of WHO Region[3]

Region	*Country*			*Biomedical engineers' density (per 10 000 population)*
Africa	Highest	1	Botswana	0.23
		2	Seychelles	0.21
		3	Ghana	0.16
	Lowest	1	Liberia	0
		2	Guinea	0
		3	South Africa	0.05
America	Highest	1	Panama	0.81
		2	United States of America	0.68
		3	Colombia	0.41
	Lowest	1	Uruguay	0.05
		2	Venezuela	0.05
		3	Haiti	0.05
Eastern Mediterranean	Highest	1	Jordan	2.51
		2	Lebanon	1.25
		3	Egypt	0.1
	Lowest	1	Tunisia	0.05
		2	United Arab Emirates	0.05
		3	Yemen	0.05

Europe	Highest	1	Israel	2.34
		2	Portugal	2
		3	Iceland	1.68
	Lowest	1	Russian Federation	0.05
		2	Tajikistan	0.05
		3	Bulgaria	0.05
South-East Asia	Highest	1	India	0.23
		2	Bhutan	0.08
		3	Bangladesh	0.05
	Lowest	1	Sri Lanka	0.05
		1	Thailand	0.05
		2	Timor-Leste	0.05
Western Pacific		3	China	4.79
	Highest	1	Japan	3.23
		2	Singapore	1.07
		3	Philippines	0.05
	Lowest	1	Republic of Korea	0.05
		2	Vanuatu	0.05

Table 5: Countries with no data on biomedical engineer density[3]

Region	*Country*
Africa	Angola
	Cabo Verde
	Central African Republic
	Comoros
	Equatorial Guinea
	Eritrea
	Gabon
	Guinea-Bissau
	Lesotho
	Madagascar
	Mali
	Mauritania
	Mauritius
	Niger
	Sao Tome and Principe
	South Sudan
	Togo
	Zimbabwe
Americas	Antigua and Barbuda
	Bahamas
	Dominica
	Nicaragua
	Saint Kitts and Nevis
	Saint Lucia
	Saint Vincent and the Grenadines
Eastern Mediterranean	Iraq
	Morocco
	Oman
	Qatar
	Somalia
	Syrian Arab Republic
Europe	Andorra
	Armenia
	Azerbaijan
	Belarus
	Kazakhstan
	Luxembourg
	Malta
	Monaco
	San Marino
	Turkmenistan
	Uzbekistan
South-East Asia	Democratic People’s Republic of Korea
Western Pacific	Brunei Darussalam
	Cambodia
	Cook Islands
	Marshall Islands
	Nauru
	Niue
	Palau
	Papua New Guinea
	Samoa
	Solomon Islands
	Tonga
	Tuvalu

Table 6: Challenges and future directions to be considered for developing staffing criteria[7,19]

Challenges	*Future Directions*
More than 4.5 billion people in the world has poor access to quality biomedical devices [7]	To develop universal health technology design for during the manufacturing of biomedical devices.
More than 70% of the devices manufactured around the globe are made with an intention to be used in the developed world	Development of stringent standards as well as single window portal for biomedical device donations
The biomedical devices sent to LMICs are mostly through donations. WHO reports states that, a great majority of the devices sent are defective and nearly 100% of them become defective within a period of 5 years due to inadequate maintenance and repair	Promotion of affordable effective and indigenous health technology whenever possible

Case study on best practices across the globe

Independent professional NGOs like Engineering World Health engages the independent professional clinical engineers to showcase their professional skills to improve global health. The organisation works to support low- and middle-income countries by providing timely servicing and maintenance of biomedical devices. As there are no standard criteria for the donation of life supporting biomedical devices, many organisations as well as HIC (High Income Countries) utilise this as an opportunity to supple defective products. The organisation focuses on providing technical training to technicians as well as engineers from low-income countries.[21]

Innovations research in Biomedical Engineering

Developments in the area of regenerative medicine, artificial intelligence integrated medical imaging and robotics are extensive timely clinical transition of the same is considered as the need of the hour.[22] Innovations shall also consider the feasibility as well. A universally acceptable biomedical device development shall consider the human resources available, environment in which it operates, material as well as maintenance resources required.[23]

Developing hazard prevention and biomedical safety

Proactive strategy to ensure all the factors related to risk of injury or illness attributable to biomedical devices are prevented. The strategy will ensure that the possible methods resulting failure risks are already been explored and safety risks for bioengineering projects are already been mapped according to the severity of effect, likelihood of occurrence and control effectiveness.[24]

Quality performance criteria and Medical Equipment Technology Management System (METMS)

Adoption of equipment performances data through the reporting of unintended incidents, disruption in the patient management due to medical device issue, extend of the downtime period happen, etc. shall be documented through METMS program. The performance outcomes assessed could be corelated with respect to the patient care outcomes and finally to the patient safety as well. The information captured through this process has the potential to contribute towards the development of guidelines for adopting and improving performance reporting.[25]

CONCLUSION

The major function of BMEs are corrective maintenance and procurement. However, since workforce recruited in LMICs are inadequate Table 5, the maintenances as well as servicing were often disrupted. The major source of supply of biomedical devices LMICs are through donations. Irrespective of maintaining the good intention of providing supplies to these countries, almost 100% of the donated device will become non-functional within a period of 5 years. This suggests the act of medical device donation shall also consider availability of qualifies staff as well as availability of consumables and spare parts to ensure the biomedical devices are reaching its desired life cycle. The research and development of happening in the arena of biomedical engineering shall be timely translated into the clinical practice and shall be made available across the globe to provide highest standard, cost effective treatment. In counties like India, who produces adequate number of biomedical engineers through education, however, translation of the graduates entering into the clinical practice are limited. The statistics show that there is a gap existing in the translation of biomedical engineering graduate to a certified biomedical engineer capable to perform the job role. The pandemic had resulted in digitalisation and better instrumentalization of medical care, it is now high time for the medical institutions across the globe to ensure appropriateness of the staffing criteria for biomedical engineers. It shall be designed after considering the patient attendance, bed strength, number of biomedical instruments used, number of medical and paramedical staff in the organisation, number of specialities and super specialities, type of patients the organisation mainly targets and other factors that determine the staffing pattern of biomedical engineers Table 6.

RECOMMENDATIONS

- A standardised job description shall be formulated for biomedical engineers as well as the technicians working in hospitals
- To develop staffing criteria for biomedical engineers. The staffing criteria shall be formulated after considering the bed strength, number of devices used in the hospital and also the nature of services provided by the hospital (for e.g., multi-speciality, super speciality hospitals)
- Performance outcome assessment of biomedical devices as well as patient care technology shall be formulated and integrated into the Standard operating practices for biomedical engineers
- Developing a compendium for common equipment

malfunctioning incidents and to provide standard operating practices for the same.

- To develop a regulatory body to ensure quality and appropriateness of biomedical equipment donating into the low-income countries. The regulation shall also mandate regarding providing servicing as well as uninterrupted supply of spare parts. A guidance document regarding possibility of refurbishing the non-functional biomedical devices and also scientific disposal of non-usable devices.
- Formulate policies to integrate biomedical engineer expert committee opinion for medical equipment procurement and utilisation in the clinical care setting.
- Each country should develop an appropriate registration criterion for qualified biomedical engineers.
- To develop academic programs on the management of biomedical devices and to ensure its availability for certification across the globe.
- Integrate biomedical engineers' certification for all major biomedical equipment used in the facilities registered under clinical establishment act. The instruments shall be calibrated and standardised on annual basis. SOPs for conducting the same shall be drafted by the proposed national council.

DECLARATION

Ethics approval and consent to participate

No primary information has been collected from any participants hence not applicable

Consent for Publication

Has been obtained from all the authors

Availability of data and materials

All the data

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research work conception and design has been provided by Dr. Kavita Kachroo. Mr. Nitturi Naresh Kumar and Mr. Mrutunjay Jena provided their inputs towards the development of the paper. Dr. Sambhu Ramesh has prepared the final manuscript. All authors reviewed and approved submission of the final version of the manuscript.

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