Biomedical Engineering Education and Practice
Challenges and opportunities in improving health in developing countries

Daniel R. Lustick and Muhammad H. Zaman

***Abstract*—While developed countries constantly pioneer new medical technologies, developing countries have been plighted with a lack of medical devices, resulting in poor health, poverty, and social inequality. Much of the medical equipment that these countries do have is broken, unusable due to a lack of electricity and infrastructure, or inappropriate for local needs. In 2000, the Global Forum for Health Research coined the term "10/90 Gap" to describe the fact that only 10% of health research funds are spent on the problems of 90% of the world's population. If the developing world is to acquire useful medical technologies, it must come from within, as the developed world has shown minimal interest in pursuing technologies for markets where the financial return is only nominal. If engineers in developed countries put their energy and resources into building the capacity of their counterparts in developing countries, they will be able to maximize their impact on the most relevant issues in global health. In order to succeed in their work abroad, biomedical engineers from developed countries must transition from being providers of solutions, to enablers of local innovation, thus contributing directly to both education and implementation. This paper addresses current challenges and appropriate solutions to tackle the lack of biomedical engineering education and innovation in developing countries.**

Keywords—appropriate technology; biomedical engineering (BME); biomedical engineering education; cross-cultural communication; international collaboration; patents; problem-solving; technology transfer; volunteer activities

I. Introduction

As the health care debate in the developed world has focused on domestic costs and [national] universal access, the spotlight has drifted even further away from the developing world and its need for greater resources for improved health. The luxury of debating universal access to health care has not yet hit most developing countries, as there is a glaring absence of the technology and infrastructure required to provide their entire populations with improved health. While developed countries delve into the realms of nanotechnology and decoding the human genome, developing countries are struggling to give x-rays—the conventional film kind—to those who need them, to provide the sick with drugs that are guaranteed not to be counterfeit, and to accurately diagnose common ailments such as pneumonia, malaria, and HIV in the field. Despite all the research and progress that has gone into medical technologies in developed countries, developing countries, which comprise a majority of the world's population, have minimal, if any, access to many of these innovations [1].

This concern over the lack of technology transfer to the developing world is not new; the reasons for it have been thoroughly documented in many papers. Nearly every paper that has covered this problem has also proposed solutions to overcoming it. Most of these solutions involve creating national-level management systems to coordinate and regulate foreign donations, open-sourcing technology to work around copyright laws, and massively subsidizing devices for the developing world with profits from the developed world. However, relatively few papers in the literature have touched on the need for robust systems of engineering and innovation within developing countries. Foreign technology can only take a resource-limited country so far; in order to be truly sustainable, innovation must be endogenous—it must come from within.

II. Background

In developing countries, over 95% of the medical equipment in public hospitals is imported, with virtually no local production [2]. Moreover, most of the equipment is inappropriate for local needs and unable to be sustained with the lack of local infrastructure. Referring to a study of donations to Columbia from 1974-1979, Pena-Mohr, of the Pan American Health Organization, points out that five years after donation, "96% of foreign-donated equipment was not working." That same study revealed that 36% of the donations did not work upon arrival due to lack of training, manuals, or accessories [2, pp. 571].

In sub-Saharan Africa alone, 70% of existing equipment is not used, while "at least half of all medical equipment in the developing world is unusable" [3, pp. 54]. What makes these statistics even more appalling is the fact that US$70-160 billion per year are spent on health research and development (R&D) worldwide [4], [5]. These data are captured in the aptly named "10/90 Gap," coined by the Global Forum for Health Research, to describe the 10% of health research funds that are spent on the problems of 90% of the world's population [4], [6].

The lack of working devices in developing countries is due to a multi-faceted, systemic failure. While the genesis of this problem has been outlined *ad nauseam*, it is necessary to

Support provided by Boston University College of Engineering and the Innovative Engineering Education Faculty Fellowship.

D. R. Lustick and M.H. Zaman are with the Laboratory for Engineering Education and Development (LEED), Department of Biomedical Engineering, Center for Global Health and Development, Boston University, Boston, MA, USA, dlustick@alum.bu.edu & zaman@bu.edu

highlight the main aspects that have created the present situation.

A. *Developed World Devices are too Expensive*

Developing countries often lack the funds to fully assess all their needs, let alone develop technologies to address their needs [1], [7]. The US$10-20 million cost of device R&D is often far out of reach of developing country budgets. Moreover, the costs of purchasing foreign devices can be prohibitive for small, publicly funded clinics and hospitals. Device manufacturers know that they will never recoup R&D costs in developing countries, thus they do not even attempt to enter the developing world market knowing they will get minimal return, if any, on their investment [8]. Similarly, due to companies determining their products by demand and market size—the market of those able and willing to pay—and not public health need [1], much R&D has gone into profitable areas such as erectile dysfunction and cosmetic surgery while leaving neglected diseases such as Chikungunya and Chagas with little attention.

B. *Lack of Supporting Technology/Infrastructure*

Electricity: While the paucity of medical devices is significant, one of the main obstacles to successful use of appropriated devices is the lack of supporting technologies and infrastructure. Unreliable electricity, including spikes and brownouts, makes it difficult to store vaccines that need to be refrigerated and necessitates expensive back-up generators and the fuel to run them. Additionally, donated units may be incompatible with local power supplies of different voltages and frequencies than their countries of origin [3]. As Malkin and Anand explained, "[The phototherapy device] would only be useful for babies born when the electricity was on, and then only those that required treatment lasting less than the time until the electricity was off again" [8, pp. 37].

Human resources: Recipients often lack the expertise and training to maintain, troubleshoot, and repair foreign devices [3], [8]. This issue is particularly true for low-income countries where skilled labor is scarce, brain drain is common, and appropriate jobs for skilled engineers and technicians are hard to find and influenced by political, tribal, and regional affiliations and nepotism. Many devices designed in developed countries require specialized technicians and tools and are not built with the intent to be fixed easily by general mechanics with only basic tools [8]. Unfortunately, curriculum in engineering and technical colleges is dated and the graduates are not able to fill the void needed in the society.

Parts availability: High-tech devices often require expensive replacement parts. Due to the rugged environments of most developing countries, the devices fail frequently and access to replacement parts is often difficult and expensive [8]. Lack of financial resources, manufacturing equipment, and capacity to fabricate parts is nonexistent. Lack of quality control also affects the quality of the parts available in the market.

Financial burden of donated devices: A donated device may cost more to maintain and use than can be afforded, thus making the donated device a greater financial burden than help, especially if the scarce resources are needed elsewhere.

C. *Devices are Culturally Inappropriate*

The common thinking that "something is better than nothing" is incorrect at best, and dangerous at worst, when used in regard to health care delivery in developing countries. The fact that resources are scarce makes it imperative that technology works well, as there are no resources to correct problems or alternatives to treatment. A recent study by Malkin and Anand found that the homemade appearance of their prototype phototherapy device elicited concerns of dubious quality and possible feelings of inferiority, making locals reluctant to use it. With no alternative treatments available, individuals were willing to forgo treatment altogether due to their concern over the appearance, and thus, efficacy of the device [8].

D. *Lack of Robustness*

Due to harsh environments (extreme temperatures, humidity, dust, etc.) in regions of many developing countries, devices that have been designed to operate in the sterile, climate-controlled work environments of many western medical facilities have very short life spans abroad [1], [8]. This is particularly true for devices that require biologics (e.g. blood, urine, live attenuated vaccines), all of which require refrigeration and frequent sterilization. These devices often fail due to the lack of necessary refrigeration and the biologics' short shelf life. The lack of capacity to maintain the devices further compounds problems due to misuse and neglect.

III. Lack of Biomedical Engineering Innovation in the Developing World

There is a clear lack of biomedical engineering (BME) education and practice in developing countries. Of the 9,659 biotechnology patents reported by the Organization for Economic Co-operation and Development (OECD) in 2008, 4,062 (42%) are from the United States, while only 97 (1%) are from India [9]. (See Table I.) Moreover, of the 194 World Health Organization (WHO) member countries, 102 (53%) have at least one BME teaching facility contact, 64 (33%) have more than one contact, and only 44 (23%) have more than two contacts [10]. The regional distribution of BME teaching facilities is illustrated in Table II. This global lack of BME teaching institutions makes it clear that there are few cohorts of biomedical engineers in the developing world to focus on issues in their own countries.

TABLE I. Patents and Teaching Facilities by Country [9], [10]

Country	***2008 Biotechnology Patents***	***Percent of Total (9,659)***	***BME Teaching Facilities***	***Percent of Total (584)***
United States	4,062	42.1	155	26.5
India	97	1.0	15	2.6
China	225	2.3	14	2.4
South Africa	18	0.2	4	0.7

TABLE II. BME TEACHING FACILITY DISTRIBUTION BY REGION [10]

Region	*# WHO Countries*	*Countries with contact*	*Countries without contact*	*Percent of countries with contact*
Africa Region	46	8	38	17
Eastern Mediterranean Region	21	9	12	43
European Region	54	37	17	69
Region of the Americas	35	29	6	83
South-East Asian Region	11	11	0	100
Western Pacific Region	27	8	19	30
Total	194	102	92	53

A. *Incorrect Paradigm of Success*

The common perception among researchers in developed countries continues to be that the criteria for successful technology are for it to be "known, effective, and economical" [2, pp. 568]. However, recent studies by "Engineering World Health" argue that this paradigm is not sufficient; explaining, "a vaccine for polio has been known, effective, and economical for many years, yet polio still plagues the developing world" [2, pp. 569], [11]. If developing countries are to obtain necessary medical technologies, developers worldwide, are going to have to understand the complexities of adoption and sustained use. "Known, effective, and economical" is an over-simplification that will only serve as an impediment in our continued work towards improved health. A lack of resources not only implies poor economic and technical capital, but also poor human resources with limited education and technical knowledge.

B. *Lack of Medical Device Management Systems*

Many developing countries lack governmental management and regulatory systems for medical devices [1], [8]. Preliminary findings of a study by the Diagnostic Imaging and Medical Devices Unit of the WHO found that:

> The majority of countries responding to the survey do not have a health technology national policy. This refers to an official written document approved at national level to guide the management of health technology related activities such as medical equipment management, planning, assessment or regulation. [12]

Of the 196 countries surveyed, 73% reported having a "unit within the Ministry of Health that manages medical devices through health technology assessment and management" [12]; while 65% have "an authority responsible for implementing and enforcing medical device specific product regulations" [12]. Though these percentages seem relatively high, it is important to note that the preliminary findings do not make a distinction between developed and developing countries. Thus, assuming that most developed countries have these institutions in place, the percentage of developing countries with these institutions is significantly lower.

This lack of medical device oversight has resulted in unregulated donations of devices of questionable quality and utility. The same WHO study found that only 42% of countries "recommended technical specifications of medical devices to support procurement or donations" [12]. Only 15% of countries adhere to WHO guidelines regarding donations, 26% have developed their own national guidelines and 58% have no guidelines for donations [12].

C. *Misguided Funding*

When it comes to medical devices, most developing countries do not need the latest, cutting-edge technologies—they often lack the funds and infrastructure to support such products, and have no mechanism to maintain the equipment and procure or manufacture replacement parts. What they need are basic, robust devices that are inexpensive and easy to use and maintain. Developing these devices consists of effectively retrofitting and stripping down existing technologies to make them appropriate to the needs and resources of the region. This process of "reengineering" merits an approach that is grounded in a rigorous engineering framework that not only builds appropriate technologies that are affordable and culturally acceptable but are also able to perform tasks in resource-poor environments. However, most R&D funding—especially the grant-based approach—aims at new, high-tech product development, not retrofitting existing products, which do not result in patents, intellectual property, and groundbreaking discoveries [8], [13].

IV. MOVING FORWARD – LOCAL BIOMEDICAL ENGINEERING

Many solutions to overcoming the lack of medical devices in developing countries have been put forth; these ideas have ranged from aggregating markets [8] to increased donation regulation and oversight [14]. This paper presents cultivating local biomedical engineers as a viable solution. While the most successful initiative is likely to take a systems approach and combine many solutions, it is crucial that endogenous BME be the keystone of any steps moving forward. As Dr. Margaret Chan, WHO Director-General, stated "progress in public health depends on innovation" [14, pp. 34], and who knows the problems, available resources, and necessities of developing countries better than their residents?

Greater endogenous BME can overcome numerous obstacles currently impeding the adoption of medical devices in developing countries. Because the private sector, especially that of developed countries, has shown relatively modest interest in investing in the public health of developing countries [7], greater local innovation will put the expertise directly in the hands of those who are adversely effected by these health problems. Local biomedical engineers will have better knowledge of the locally available resources needed to develop and maintain technologies, as well as the cultural context in which the technology must be adopted. Moreover, in the United States, the Food and Drug Administration (FDA), requires that all devices manufactured exclusively for use abroad, be able to obtain their approval. Though the devices do not have to obtain the approval, but simply be able to, it is still prohibitively expensive to get a device through all the trials and

regulations in order to comply. The most obvious way around this obstacle is developing and manufacturing devices in other countries instead of trying to recoup R&D and testing costs by selling at exorbitant prices to developing countries [8]. Finally, people support what they create. Educating and empowering local engineers to solve the most pressing issues of their communities is the best way to ensure that the technologies will be adopted [7]. Local BME education is the most important component of a multi-pronged strategy to increase innovation and robustness of medical technologies.

While a significant majority of developing countries have engineering programs, they are not tailored to engineering in the health sector. The output of these institutions is engineers who have little, if anything, to contribute to the local biomedical markets. Similarly, technician-training programs in developing countries have focused largely on the electrical and mechanical technical markets with little emphasis on the biomedical sector. Furthermore, lack of integration between doctors, hospital managers, ministries of health, and the technical education sector has resulted in disjointed and poorly managed efforts at the national level.

In order to foster greater local BME, there are certain challenges that must be acknowledged.

A. *Useful Technology is Better than "Cool" Technology (Cool and Useful is the Best)*

The western fascination with new, cutting-edge technology has led to engineers from developed countries often assuming people in developing countries have the same needs and desires. Understanding the social and environmental context within which the device will be used is critical to successful adoption and continued use; focusing on device utility, rather than cutting-edge innovation is what is needed the most [1]. However, a device that is both useful and "cool" presents the greatest opportunity for success.

B. *Technological Versus Social Interventions*

There is a lack of consensus regarding the role of technologic interventions as compared to social interventions (microfinance, education, etc.) and increased social services [2], [6]. Increased endogenous BME incorporates both approaches—focusing on increased social capacity to increase technologic output.

V. Criteria for Success

There is no one-size-fits-all method for fostering greater endogenous BME. However, in order for this concept to take hold, certain criteria need to be met.

A. *Strong Partnerships and Local Ownership*

Successful interventions require that local institutions and companies find partners that have appropriate and useful skills as well as resources [3]. While international partnerships are appealing due to currency exchanges and access to different resources, domestic partnerships can also be utilized to ensure successful interventions and initiatives. As with any intervention, there must be local ownership and participation in order for there to be success [3]. This is especially important in regard to BME for developing countries, as many of the problems thus far have been a result of a lack of local ownership and voice in global BME [13].

B. *Greater Access to Research and Literature*

In order for local engineers to maximize their impact, they must have greater access to state-of-the-art research and literature [13]. Valuable time cannot be lost working with outdated and incomplete data. Though the Internet has greatly improved access to literature and research, much still remains inaccessible to many institutions in developing countries [13]. Increasing access to current academic journals for both academic institutions with programs such as HealthNet News, which features free peer-reviewed literature for health workers in low and middles income countries, is paramount [15].

C. *Device Criteria*

Many institutions have put forth guidelines for medical devices for developing countries. The criteria developed by the WHO, World Bank, UNICEF, and UNDP for infectious disease diagnostic devices for developing countries, is that all devices be ASSURED:

- Affordable
- Sensitive
- Specific
- User-friendly – simple to perform in a few steps with minimal training
- Rapid and Robust – enable treatment at the first visit
- Equipment-free – easily collected non-invasive specimens (e.g. urine, saliva)
- Deliverable – to end-users [16]

Others have added to this list that the devices be available long-term, of adequate and consistent quality [7], and look professional [8]. It is vital that engineers take these criteria into consideration when developing medical devices. Because local engineers are more aware of material availability, cultural appropriateness, and potential for acceptance and continued use, they are best equipped to design devices that will be adopted in their countries.

VI. Potential Approaches

The goal of this paper is not to present a singular way of improving the lack of medical devices in developing countries. Others have put forth their ideas to confront this issue, all of which show potential for success. However, it is the combination of many of these approaches, plus others not listed here, which will foster improved global health.

A. *Developing World Academics Add to Leading Research*

Fostering greater endogenous BME is not limited to the laboratory; academics from developing countries must add their knowledge and experience to the ever-growing knowledge-pool of BME research [13]. Garnering support, whether financial or otherwise, is always easier for high-profile problems such as HIV/AIDS and malaria. Local academics

have the ability to raise status of region-specific problems to a higher profile; this will help gain the support of regional and international partners [7].

B. *Partner with Foreign Institutions and Companies*

If BME institutions can partner with commercial companies they can gain access to greater resources and thus create lower-cost technologies [7]. Additionally, partnering with BME institutions in developed countries will allow for a greater exchange of resources and ideas; this would also give the developed country schools potential access to field-testing [8]. The Indo-US Collaboration for Engineering Education (IUCEE) runs courses taught by American engineering professors for their Indian colleagues to learn new ways of teaching engineering [17]. This exchange also allows American professors to gain a better understanding of the issues facing other populations. Recently, the U.S. Department of Health and Human Services partnered with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) to roll out the Medical Education Partnership Initiative (MEPI). This initiative awards grants to institutions in Sub-Saharan Africa to develop or enhance their medical education programs [18]. A similar program for BME programs would be a means of strengthening local capacities in this field.

C. *Utilize Volunteer Groups*

Student groups, such as Engineers Without Borders, not only give students from developed country institutions an opportunity to apply their skills in low-resources areas, but they also provide local engineers with access to aspiring engineers who have had unfettered access to the latest research and ideas. This opportunity has the potential to make a strong impact on both parties; the key is for the visiting engineers to teach, not give handouts.

VII. Conclusion

In order to confront the numerous factors that have led to the current lack of medical devices and innovative capacity in BME in the developing world, a truly systemic approach must be taken. The cornerstone of this approach needs to be increasing local capacity for BME, both in terms of education and practice of the discipline. Greater endogenous BME has the potential to narrow the medical device chasm between developed and developing countries while simultaneously building the capacity of local people. Solving the medical device dilemma will result in much-improved public health and greater global equity.

Acknowledgments

The authors are grateful to LEED members for many insightful discussions.

References

[1] World Health Organization Department of Essential Health Technologies, "Medical devices: managing the mismatch – an outcome of the Priority Medical Devices project," WHO, Geneva, Switzerland, 2010 [Online]. Available: http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf

[2] R. A. Malkin, "Design of health care technologies for the developing world," *Annu. Rev. Biomed. Eng.*, vol. 9, pp. 567-587, 2007. doi: [10.1146/annurev.bioeng.9.060906.151913]

[3] S. Howie *et al.*, "Beyond good intentions: lessons on equipment donation from an African hospital," *Bull. World Health Organ.*, vol. 86, no. 1, pp. 52-56, Jan. 2008. doi: [10.2471/BLT.07.042994]

[4] L. Doyal, "Poverty and health from a gender perspective," in *The 10/90 report on health research: 2001-2002*, S. Davey, Ed., Global Forum for Health Research, Geneva, Switzerland, 2002 [Online]. Available: http://www.globalforumhealth.org/content/download/547/3541/file/s14792e.pdf

[5] S. A. Matlin and G. M. Samuels, "The Global Health Research and Innovation System (GHRIS)," *The Lancet*, vol. 374, no. 9702, pp. 1662-1663, Nov. 2009. doi: [10.1016/S0140-6736(09)61912-7]

[6] A. S. Daar *et al.*, "Top ten biotechnologies for improving health in developing countries," *Nature Genet.*, vol. 32, no. 2, pp. 229-232, Oct. 2002. doi: [10.1038/ng1002-229]

[7] M. J. Free, "Achieving appropriate design and widespread use of health care technologies in the developing world. Overcoming obstacles that impede the adaptation and diffusion of priority technologies for primary health care," *Int. J. Gynaecol. Obstet.*, vol. 85, sup. 1, pp. S3-S13, Jun. 2004. doi: [10.1016/j.ijgo.2004.01.009]

[8] R. A. Malkin and V. Anand, "A novel phototherapy device," *IEEE Eng. Med. Biol. Mag.*, vol. 29, no. 2, pp. 37-43, Mar.-Apr. 2010. doi: [10.1109/MEMB.2010.936453]

[9] Organisation for Economic Co-operation & Development, "Patents by regions," OECD, Paris, France, 2011. doi: 10.1787/data-00509-en

[10] World Health Organization Department of Essential Health Technologies, "Biomedical and clinical engineering institutions and associations worldwide," WHO, Geneva, Switzerland, 2011 [Online]. Available: http://www.who.int/medical_devices/support/en/index.html

[11] E. Renne, "Perspectives on polio and immunization in Northern Nigeria," *Soc. Sci. & Med.*, vol. 63, no. 7, pp. 1857-1869, Oct. 2006. doi: [10.1016/j.socscimed.2006.04.025]

[12] World Health Organization Department of Essential Health Technologies, "Preliminary results of the baseline country survey on medical devices," WHO, Geneva, Switzerland, 2010 [Online]. Available: http://www.who.int/medical_devices/survey_preliminary_results/en/index.html

[13] J. J. Miranda and M. J. Zaman, "Exporting 'failure': why research from rich countries may not benefit the developing world," *Revista de Saúde Pública*, vol. 44, no. 1, Feb. 2010. doi: [10.1590/S0034-89102010000100020]

[14] World Health Organization Department of Essential Health Technologies, "Landscape Analysis of barriers to developing or adapting technologies for global health purposes," WHO, Geneva, Switzerland, 2010 [Online]. Available: http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.13_eng.pdf

[15] AED-SATELLIFE, "Center for Health Information and Technology: HealthNet News," 2011 [Online]. Available: http://www.healthnet.org/e-newsletters

[16] World Health Organization Sexually Transmitted Diseases Diagnostics Initiative, "About SDI: Priorities," UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, Geneva, Switzerland, 2009 [Online]. Available http://www.who.int/std_diagnostics/about_SDI/priorities.htm

[17] Indo-US Collaboration for Engineering Education, "IUCEE Website," IUCEE, Bangalore, India, 2007 [Online]. Available: http://iucee.org/

[18] Fogarty International Center, National Institutes of Health, "Medical Education Partnership Initiative (MEPI)," 2011 [Online]. Available: http://www.fic.nih.gov/Programs/Pages/medical-education-africa.aspx