Journal of Medical Devices

Guest Editorial

Special Issue: Medical Devices for Economically Disadvantaged People and Populations: Perspective Problems and Prospective Solutions

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Overview and Objective

Advances in science and technology have led to phenomenal breakthroughs in medical device technologies that allow clinicians to image, diagnose, and treat pathologies like never before. Complex approaches such as modern surgical robots [1], exoskeletal prostheses [2], and magnetic resonance imaging (MRI) systems [3] provide treatment options unimagined two generations ago; complicated interventions such as left ventricular-assisting devices [4], irreversible electroporation [5], implantable nanotechnology [6], and enhanced preservation strategies of organs for transplants [7] dominate popular science. However, much of this intricate technology comes at a high price tag only accessible to a small percentage of the world's patients. Projections indicate that the total worldwide cost burden of medical devices will reach over $510 billion in 2020 [8].

The increasing cost of medical technology has led to a surge in total healthcare expenditures in most economically developed countries. Health cost in Organization for Economic Co-operation and Development (OECD) member countries grows faster than their corresponding gross domestic products (GDP). In the USA, healthcare expenditures in 2019 amounted to 17.7% of its GDP [9]. This is exacerbated by the uneven wealth distribution in the world. The October 2019 Global Wealth Report from Credit Swiss [10] reports that the top 1% of the population own 45% of the global wealth, the richest 10% own 82%, and the bottom half hold less than 1%. While the wealthy and upper middle class have access to costly medical technology, the poor do not benefit from these advances, particularly within high-income countries with privatized healthcare [11]. The increasing cost of medical devices is disproportionately affecting economically disadvantaged people around the world. As of 2017, over half of the world population is too poor to access health services and related expenses are impoverishing hundreds of millions [12]. Among those that can afford healthcare, nearly a billion people spend 10% or more of their household income on health expenses for themselves or a family member. For almost 100 million of these, the expenses are high enough to push them into extreme poverty, forcing them to survive on the equivalent of just $1.90 or less a day [13].

The objective of this special issue of the *Journal of Medical Devices* is to alert and provoke the engineering community regarding the healthcare needs of economically and sociologically disadvantaged populations (ESDPs). Many of the findings and discussions relevant to medical devices in ESDPs are published outside the engineering community. However, it is the opinion of these editors that a concerted engineering effort is essential to addressing and overcoming the current challenges being faced. This introduction was written to highlight reports from other fields on some of the common medical device issues and technological obstacles within ESDPs and provide a preface to the issue's articles showcasing relevant, current advancements from the engineering community. In addition, this section is intended to direct our readers to sources and sites typically unfamiliar to engineers and motivate increased activity within this field.

Global Issue Recognition

While the wealthy and upper middle class of both economically advantaged and disadvantaged countries have access to costly medical device technologies, the poor do not benefit from these advances [11]. It is interesting to note that while major U.S. philanthropic organizations focus on improving healthcare in economically disadvantaged parts of the world, the healthcare available to their domestic poor is frequently overlooked [14]. The fact that Native American Reservations are a recognized "food desert" without access to staple essentials such as fresh produce is often ignored [15,16]. In global food studies, diabetes is a recognized epidemic among the poor in emerging and developing countries. As described by Narayan et al., highly processed food and refined grains are being subsidized by many countries. Although five portions of fruit and vegetables are recommended each day, the current global production is unable to meet this demand, and the discrepancy between supply and demand is greater in developing countries [17]. A possible solution to type II diabetes within these populations could be found through innovations in food technology. The ability to feed the current world population is mainly due to the 20th century advances in farming and refrigeration technology. Implementing advances in cryopreservation, such as those discussed in the UNESCO group report on cryobiology in this issue, could lead to breakthroughs in food preservation. This is an area in which engineers could make major contributions, such as those described in Bilbao-Sainz et al. [18].

The WHO is one of the primary organizations dealing with medical device technology issues in ESDP [19]. In the WHO official 13th Program of Work for 2019–2023, they described the reliance of the world on medical devices for achieving goals of univeral health coverage, emergency response, and safeguarding the population. They passed resolution WHA60.29, wherein the various member states gave recognition to the fact that medical devices are a necessity for proper delivery of modern health care, but also to the significant obstacles regarding their use, regulation,

and selection [19]. While medical devices are indispensable to healthcare, many device technologies are inaccessible to the majority of people who need them, particularly in low- and middle-income countries (LMICs) and among the poor in high-income countries [20]. The 4th WHO Global Forum on Medical Devices entitled "Increasing Access to Medical Devices" was held in December 2018 to address this challenge [21]. One outcome of interest to this readership was the creation of a list of priority medical devices,[1] divided by country and focus area (e.g., cancer, aging, or diagnostic imaging, among many others). Other relevant publications from the WHO include "Delivering quality health services: a global imperative for universal health coverage" [22] and "Barriers to innovation in the field of medical devices" [23]. A related exploration was published by *The Lancet* in 2018, in which an analysis of global causes of premature death is given. Analyses segment populations globally, by region, and by nationality, providing a perspective on the medical device technology needs in different parts of the world [24].

Gaps in Current Solutions

A comprehensive review of the current gaps in global solution strategy would take far more than these few pages of introduction. However, we will discuss a few examples for illustration. One of the main advances in modern medicine is medical imaging. Currently, medical imaging is required for correct diagnostics in 20–30% of cases worldwide, whereas half the world population have no access to the technology [25–27]. Organizations and commercial companies have been established to address this issue, such as RAD-AID International and the Pharmaceutical and Therapeutics Community. One problem with these efforts is that many companies and organizations try to address the need through direct equipment donations. In the personal experience of one of the authors of this introduction (BR), an urgent phone call was received from Haiti days after the major earthquake in 2010. The caller was a medical care provider that stated they had received a new state-of-the-art ultrasound system, but there was no one at the clinic that knew how to operate it. This is not an unusual issue, as many articles in recent years have described similar circumstances, as well as exploring equipment breakdown due to poor maintenance and effective training programs for operation and upkeep [28–33].

While true for medical imaging, these issues affect all types of medical devices. Ademe et al. [34] provides a case study review on availability and utilization of medical devices in Eastern Ethiopia. Nearly 300 medical devices were surveyed in three regional hospitals. The authors decribed a dire situation wherein over a third of the medical devices within the three hospitals examined did not function. This was attributed to purchasing based on bidding going to the cheapest contracts, a lack of expertise in operation and maintenance, overworked staff, and inconsistent availability of electrical power [34]. A report by Zomboko and Tripathi [35] describes similar challenges in a Tanzanian hospital. The essence of the findings were that local caregivers were not using donated equipment due to dissatisfaction with the quality of equipment received, lack of training support, poor communication channels with donors and manufacturers, and lack of strategy in selection regarding incoming equipment [35]. This article represents a repeated theme in all issues related to the device technology for ESDP, particularly in low-income countries. Beyond issues in the quality and operation of donated equipment, historical approaches have utterly disregarded sustainability. This disconnect between engineers, manufacturers, and ESDP users is natural, as most medical devices are motivated by economics and designed for high-income populations. Another common issue is that purchases are made through bidding processes tuned for selection of the least expensive systems. However, these less expensive devices are often of low quality and fail soon after purchase, resulting in lack of availability for patients and a discouraging loss of investment by those seeking to improve the situation. These issues are explored in great detail in several outstanding review papers [36–39] and organization reports [10,40]. It is imperative that we as engineers spearhead development of solutions that are reliable, simple, and cost effective in design.

New Solutions and Strategies for Increased Impact

While "fire and forget" donation programs have recognized flaws, better solutions to the issues of healthcare for ESDPs are possible at several levels. In general, healthcare costs must be reduced, but this is only practically achievable through sustainable, continuous programs. In specific, solutions could seek to leverage and improve existing technologies to be more versatile, such as the smartphone. The smartphone has had unprecedented market penetration into many ESDPs, even in low-income countries. For example, many groups have utilized it as a platform for accessible, low-cost ultrasound [27,41,42]. Others have used smartphones as the foundation for innovative systems enabling microscopy, sensing, and diagnostics [43–45]. Another technological approach with high potential is diagnostic microfluidics, which can utilize smaller sample volumes while conversely producing more sensitive analyses [46–48]. Many groups have developed diagnostic microfluidic platforms with an eye toward lowering cost per sample, an excellent example is described by Gonzalez et al. within this issue. Furthermore, the explosion of paper-based microfluidic platforms also holds great promise for ESDPs [49–52]. Other highly relevant advances are being made in point-of-care diagnostics, emergency trauma interventions, and personalized medicine [53–56]. Some fields that have great potential for impacting ESDP medical care in the longer term are deep learning and artificial intelligence, where groups are already developing algorithms for diagnosis and the provision of medicine at lower costs [57–61]. These approaches address a key need in ESDPs by reducing the burden on having expert physicians and nurses available, and even can be developed to detect fake or insufficiently tested medicines, a problem currently plaguing developing countries [62,63].

Other fields ripe for innovation in ESDPs are prosthetics and orthopedics support devices. This SI showcases work developing low-cost arm rehabilitation systems, 3D-printed hand prostheses, and improved, frugal liners for lower leg prostheses. Other articles exhibit novel intrauterine tamponade designs for treating postpartum hemorrhage, low-cost oxygen blenders for infant bubble continuous positive airway pressure circuits, and task-shifting devices for enabling the insertion of subcutaneous contraceptive implants by less skilled caregivers. The issue includes manuscripts describing the development of reusable core needle biopsy devices, low-cost electrosurgical units, and inexpensive gene sensors for label-free cDNA detection. A two part series of review articles examine the applications of cryobiology in both cryogenic preservation of living tissues and cryosurgery in ESDPs. These are just a sampling of the excellent work compiled into this issue comprising 18 research articles, reviews, technical briefs, and expert views on some of the most impactful and relevant medical devices currently in development for ESDPs.

Conclusion and Acknowledgments

The goal of this SI of the *Journal of Medical Devices* is to alert our engineer colleagues to the potential and need for medical device innovations with a perspective toward ESDPs. Obviously, we were limited to addressing a minuscule part of the greater field in this single issue. As discussed, the obstacles presented by the lack of affordable health care to the majority of the world's population, when juxtaposed with uneven distribution of wealth and the high cost of advanced medicine, has been well-documented in numerous publications from researchers and altruistic organizations alike. However, it is our belief that engineers are among

[1] https://www.who.int/medical_devices/priority

those with the most relevant and applicable training for developing practical technological solutions to reduce the cost of medical technologies without sacrificing quality and efficacy. The belief has motivated this attempt to bring these problems into the discussion within our engineering community, and hopefully inspire greater engagement and involvement.

This SI includes impactful articles by leading researchers in fields of high relevancy to ESDPs. These were carefully chosen from among many other valuable articles, briefs, and reviews submitted that could not be included, primarily due to being outside the focused scope of this issue. The guest editors would like to thank the many dedicated reviewers who offered their time and expertise in review. The insightful guidance of the Co-Editors Drs. Rupak Banerjee and William Durfee was invaluable, as was the support by the ASME editorial staff. We believe this SI addresses frequently ignored truths outside the popular focus on flashy innovations and disruptive high technology. We charge the engineering community to reconsider pursuit of the rigorous testing and development of simple, elegant solutions to reduce healthcare costs in ESDPs, in both economically disadvantaged and advantaged countries alike.

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