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The Kahawa Declaration: a manifesto for the democratization of medical technology

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Abstract

Most medical technology is employed and accepted passively by patients and doctors who have little or no influence in its design or usability. Patients are not involved in the development of medical technology, which is undertaken behind closed doors and whose global impact is hindered by proprietary know-how and by costs. This has so far impeded equitable healthcare as most of the world does not have access to the technology or healthcare coverage. Understanding the relevance of international partnerships for achieving the Sustainable Development Goals, feeling specially committed to the promotion of the Goal on "Good Health and Well-Being", and convinced about the role that open-source biomedical engineering approaches may play in the future of medical technology, we commit ourselves, through the Kahawa Declaration, to enlighten the transformation of the biomedical engineering field, towards the democratization of medical technology as a key for achieving universal equitable health care. This paper presents the content of the Kahawa Declaration, which was signed in Nairobi in December 2017.

Keywords: open-source medical devices; global health coverage; equitable health care; democratization of medical technology

Introduction

According to the Universal Declaration of Human Rights (Article 25), "…everyone has the right to a standard of living adequate for the health and well-being... including food, clothing, housing and medical care…" (United Nations General Assembly, 1948); such rights should be deeply rooted in human nature and it is our duty making them true. However, universal health care is still a dream far beyond reality, even if all United Nations Member States have agreed to pursue the achievement of universal health coverage by 2030, as part of the Sustainable Development Goals (United Nations, n.d.). Currently, around 60 countries offer health care and financial protection to all their citizens, but vast regions, accounting for more than the 80% of the World's population, still live without the desired universal coverage.

Scientific-technological discoveries and derived mass-produced goods, to be consumed both offline and online, are advancing at a rapid pace. Nevertheless, with regard to social improvement and well-being, relevant additional efforts are required for stagnation to be avoided, for further progress, and for adequately management of the challenges ahead; the latter includes climate change, population growth, the unstable global political panorama and the potential illicit uses of technology, communication and artificial intelligence (Gore, 2013). Technological advances bring new unknowns to the current state of global health. Illegal traffic of organs, accounting for around a 10% of the transplantation surgeries performed worldwide; criminal activities linked to cyber and biological weapons; piracy of medical devices, especially in connection to those managed by software; mass-production of reverse-engineered biodevices, which constitute infringements of intellectual property; fraud and theft of personal data of patients; among others, are some of the international problems that increase in complexity as technology progresses.

To avoid reaching a point of no return, urgent actions are needed to prepare ourselves for the future of a mankind approaching a technological singularity (Kurzweil, 2005), whose impact on health and related global concerns can be both positive and negative. Leaning the scale in the right direction requires international and coordinated efforts, as well as passionate professionals concerned about a future in which universal health care becomes a fact.

In response to the realities outlined above, the Kahawa Declaration expresses principles for the democratization of biomedical technology, recognizing it as a key to equitable healthcare. It was first unveiled in Kahawa in Nairobi on the 15th of December 2017 and signed by 22 individuals from different countries, mainly scientists and engineers. It is not a regulatory document and does not represent the official policy or opinion of any institution, although it may support the establishment of foundations towards towards recommendations for policy makers. Signatories of the declaration agree personally to promote and support open healthcare and technology and we invite scientists to adhere to this declaration at the following website: http://ubora-biomedical.org/kahawa-sign-page. Their names will be added to the list of signatories.

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Hope

Recent groundbreaking developments in the biomedical engineering field and in the use of technology for managing and solving complex health problems, fill us with hope. The development of medical imaging and related diagnostic improvements, the connection of medical images with computer-aided design and digital manufacturing resources for personalized prostheses, the advances in computer-assisted surgical planning and computer-guided-surgery, the progressive implementation of e-health procedures, the design of multi-functional bio-nano materials and structures for treating cancer, and the advent of tissue engineering and biofabrication, to cite just some examples from the last three decades, help to highlight the radical innovations we are experiencing and let us envision the priceless potential of technology applied for improving healthcare. In most cases, these advances have been achieved in a collaborative way and have led to more effective and resource-efficient ways of fighting against disease and of improving people's health, hence providing cheaper alternatives to state-of-the-art procedures. The positive socio-economic impacts of scaling up these technologies reaffirm our vision of universal health coverage, while some recent successful experiences show us the path towards a fairer and more sustainable future of healthcare and inspire us to devote ourselves to its construction. Among these influential proposals, we can cite the 3D printed prostheses developed by the e-NABLE Community (http://enablingthefuture.org), the sharing of good practices within the Patient Innovation Forum, pioneering projects for promoting open-source bioengineering (De Maria et al., 2014; De Maria et al., 2015, Ravizza et al., 2017), educational experiences searching for more democratic paradigms (Díaz Lantada, 2016), and innovative collaborative frameworks, of which the African Biomedical Engineering Consortium (http://www.abec-africa.org) presents an inspiring example.

This manifesto is written under the influence and optimistic (yet realistic) insight of the aforementioned pioneers, with the hope of making universal health coverage possible in the next decades. The call for action proposed in the following paragraphs is deeply connected with some of the most relevant and urgent Sustainable Development Goals of the United Nations, including: "Good health and well-being", "Quality education", "Decent work and economic growth", "Reduced inequalities" and "Partnership for the goals".

Call for Action

Collaborative Biomedical Design Methodologies for Global Health Concerns

Collaboration is essential for successful engineering of complex projects; the biomedical engineering field stands out given the need for multidisciplinary teams capable of systematically addressing the development of medical devices considering medical, social, economic, technical, safety and regulatory issues. International collaboration in this field, together with the involvement of potential stakeholders (i.e. patients, patients' associations, medical professionals, policy makers, citizens), also leads to advantages including: the incorporation of pertinent opinions for obtaining user-oriented devices with improved results, the involvement of local populations for accelerating the uptake of innovative medical devices, and the assurance that socially relevant health concerns do not remain unattended.

Considering that cooperation is not always straightforward, it is vital to support the generalization of product development techniques aimed at simplifying collaborative design tasks. Technology can again assist us, especially if we employ online platforms and resources for co-design activities and for collaborative projects, but the role of educators is also fundamental. Providing the biomedical engineers of the future with a broad cultural background will assist them in understanding the benefits of diversity and facilitate their interaction with colleagues and stakeholders from other cultures and environments. Training them in teamwork and communication and making them aware of the social impact of engineering decisions, for instance by means of multi-faceted and complete project-based learning strategies, such as those following the conceive-design-implement-operate approach (Crawley et al., 2007), and having them experience the collaborative development of real biomedical devices (Díaz Lantada et al., 2016), would contribute to a global strategy towards improved biodevices addressing global health challenges. We propose working in these directions, complementing the basic scientific-technological aspects of bioengineering education with an additional focus on important attitudes, skills, techniques and tools for collaborative professional practice, always highlighting the social role of engineering practice and the need for collaboration with other professionals. And we call for support in pursuing this objective.

Development of Open-access E-infrastructures for Global Action

The development and employment of adequate data management strategies and of methodologies for improved information sharing is intimately connected to the construction of healthy, sustainable, creative, effective and efficient collaborative design environments. Special challenges arise when working in the cloud or collaborating online within the medical sector, where additional emphasis has to be placed on protecting sensitive data of patients. Developing user-friendly, versatile, stable and safe open-access e-infrastructures, for supporting these online interactions in the collaborative development of biomedical devices, and following FAIR (findable, accessible, interoperable and reusable) data principles, are appropriate directions for achieving global action towards the democratization of medical technology.

A more widespread use of collaborative (and innovative) e-infrastructures may also be beneficial for promoting impacts and for finding new ways of funding research translation to market and, in the case of biodevices, for reaching patients in a more efficient, safe and rapid way. Crowd-funding can be implemented within these e-infrastructures, such as the approach being developed in the UBORA project (Ravizza et al., 2017; http://ubora-biomedical.org) together with other sponsorship options, including patrons funding specific projects or public/private organisations deciding to fund research and development activities in a concrete medical area, as part of their social responsibility strategy. Devoting funds for expanding the teaching-learning potential of these online infrastructures should be additionally explored, to achieve the democratization of medical technology, as we detail further on. Mutual support among e-infrastructures pursuing universal health coverage will prove essential.

Biomedical Engineering Education for All

Reinventing the biomedical engineering field, and consequently medical practice, by a systematic promotion of open-source medical devices and of collaborative design methodologies, requires training of the best possible professionals, which will be those most talented and passionate about the impact of medical technologies for solving worldwide health issues. This gathering of genius and motivation cannot be hindered by reasons linked to social status, race, religion, political opinions, sex or sexual orientation. Consequently, access to high-quality biomedical engineering education should be promoted and high-quality teaching-learning resources and materials should be made widely available. Connection of potential students to networks of educators with a background in this field and pursuing the objectives here detailed should also be granted and encouraged. Recent technological advances and paradigms, including social networks for collaborative learning and massive open online courses, may support the training of a new generation of biomedical engineers, capable of creating scientific-technological advances beyond the state-of-the-art, and skilled in nurturing these advances for the benefit of health care and society.

Achieving this milestone is a first step towards a cohort of well-trained biomedical engineers aware of the relevance and benefits of international alliances and of widely accessible medical technologies. We will support this objective by means of annual open design schools, focused on medical devices, which will be accessible on the basis of merit, after design competition rounds. These schools may be expected to influence programmes of study worldwide in the collaborative design of open-source biomedical devices.

Harmonization of Medical Device Directives and Accessible Standards

Constructing a framework for enabling medical technologies to reach everyone, everywhere, relies on the use of common design practices and on the fulfilment of broadly accepted regulations that warrant patients' safety and allow for compliant devices to be commercialized and applied worldwide. Consequently, efforts aimed at the global harmonization of regulations, which should also take account of the particularities of collaboratively developed devices, are additional keys for success. In fact, collaboratively developed projects may well result in safer devices if the correct principles are followed (Ravizza et al., 2017). In addition, if we pursue a democratization of technologies, standards, which support designers in the development of compliant devices, should be reformulated and made widely available, even for free, as compliance with regulations is compulsory and paying for access to standards prevents equality of opportunity. Ideally, standards should be concentrated on patient safety and motivate designers to find more creative solutions, while guiding them in the design process of effective devices. However, large multinationals and their lobbies influence the development of standards, which may result in barriers to entry for smaller or newer competitors. Establishing networks for supervising the standardization process and for developing open-source standards may well be another side of the global solution, as has proved successful in other industries, such as the software one and the example of Linux (https://www.linuxfoundation.org).

International Partnerships for Achieving Universal Health Care

Collaboration in medical device development should affect the complete life-cycle of the products being developed, from the conceptual design stages and the basic engineering aspects, to production, testing, commercialization and operation. For transforming collaborative design into collaboration through the whole life-cycle, biomedical engineers have to partner with: medical boards and patient associations for tackling pertinent needs, policy makers and regulatory experts for obtaining legal support, NGOs and local populations for introducing the products and managing the supply chain, large infrastructures for systematic testing, manufacturing facilities with open-access schemes (i.e. fab-labs), and patrons and sponsors, among others. This requires additional multidisciplinary and international partnerships for increased impact and is deeply connected with the immediate actions proposed in the following section.

Future

Given the call for action and its urgency, we propose the following immediate actions, as a foundation for rebuilding medical technology towards our mid- and long-term objectives:

- Sign and assume the present manifesto, as a symbol of commitment for future collaboration ensuring students worldwide learn and live through the complete development process and related design methodologies of innovative medical devices in a collaborative way and within an international environment.
- Develop and mobilise a fundamental tool for empowering novel collaborative design strategies in the biomedical field and for sharing innovative medical devices developed with open-source criteria, and open it to collaborators pursuing the democratization of medical technology (e.g. the UBORA e-infrastructure of the UBORA project).
- Align forces and support international collaboration in the field of accessible medical technology through mobility actions, such as the African Biomedical Engineering Mobility project (Douglas et al., 2017; www.africanbmemobility.org), training schools and international congresses on open-source biomedical engineering.
- Disseminate advances linked to collaborative biomedical engineering and open-source medical technologies for improved sharing of good-practices, not only resorting to international conferences, but also opting for open-access publication of progress in this field and by establishing a new open journal focused on these topics.
- Pursue the aims highlighted in this document, supporting our partners, promoting collaboration with significant stakeholders (from patients, patients' associations, medical professionals and biomedical engineers, to educators, policy makers, manufactures and companies), working towards universally accessible, intrinsically safe and high-quality medical technologies and solving unforeseen challenges with a balance between pragmatism and idealism (pedes in terra ad sidera visus).

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