

# **THE KAHAWA DECLARATION: A MANIFESTO FOR THE DEMOCRATIZATION OF MEDICAL TECHNOLOGY**

**Joint Declaration of the UBORA and ABEC partners**  
*Presented and signed at Kenyatta University, December 2017*

## **EXECUTIVE SUMMARY**

Most medical technology is passively employed and accepted by patients, doctors and engineers who have little or no say in its design or usability. In addition, 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. Indeed, the benefits of quality medical technology today are only enjoyed by 20% of the world's wealthier population. Understanding the relevance of international partnerships for achieving the Sustainable Development Goals, feeling specially committed with 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, according to the objectives and actions explained in present 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.

## **CONTEXT**

According to the Universal Declaration of Human Rights (Article 25) [1]: "...everyone has the right to a standard of living adequate for the health and well-being, including food, clothing, housing and medical care...", 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 [2], as part of the Sustainable Development Goals. 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.

## **URGENT NEEDS**

Our World seems to be advancing at a rapid pace, especially in terms of scientific-technological discoveries and derived mass-produced goods, to be consumed both offline and online. Nevertheless, regarding social improvement and well-being, relevant additional efforts are required to avoid stagnation, to progress further on and to adequately manage the challenges ahead, which include: the climate change, the population outgrowth, the global unstable political panorama and the potential illicit uses of technology, communication and artificial intelligence [3].

These technological advances bring new unknowns to the current state of global health concerns. 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 and communications progress.

To avoid reaching a non-return situation, urgent actions are needed to face these fundamental issues and to prepare ourselves for the future of a mankind approaching technological singularity [4], whose impact on health and related global concerns, according to present situation and available examples, 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.

## **HOPE**

But fortunately enough, recent groundbreaking developments in the biomedical engineering field and stimulating uses 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 guided-surgery, the progressive implementation of e-health procedures, the design of multi-functional bio-nano materials and structures for treating cancer or 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 potentials 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 extremely positive socio-economical impacts of scaling up these technologies reaffirm our vision of universal health coverage and 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 [5], the sharing of good practices within the Patient Innovation forum [6], pioneering projects for promoting open-source bioengineering [7-9], educational experiences searching for more democratic paradigms [10], and innovative collaborative frameworks, for which the African Biomedical Engineering Consortium (ABEC) constitutes 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 United Nations [11], including: “Good health and well-being”, “Quality education”, “Decent work and economic growth”, “Reduced inequalities” and “Partnership for the goals”, as further explained.

## **CALL FOR ACTION**

### **1) Collaborative biomedical design methodologies for global health concerns**

Collaboration is essential for successful engineering of complex projects and the biomedical engineering field stands out for the need of multidisciplinary teams capable of systematically addressing the development of medical devices considering medical, social, economical, technical, safety and regulatory issues. International collaboration in this field, together with the adequate 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 for distributing wealth and the warranty 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 is needed for helping them understand the benefits of diversity and for facilitating their interaction with colleagues and stakeholders from other cultures and environments. Training them in teamwork and communication skills and making them aware of the social impact of engineering decisions, for instance by means of multi-faceted and very complete project-based learning strategies, such as those following the conceive-design-implement-operate approach [12], letting them live through the collaborative development of real biomedical devices [13], can be a basic aspect of the 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.

### **2) 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 for 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 seem right directions for achieving global action towards the democratization of medical technology.

A more widespread use of collaborative (and innovative) e-infrastructures may be also of help for promoting impacts and for finding new ways of funding research translation to market and, in the case of biodevices, for helping reach patients in a more efficient, safe and rapid way [5-6, 9]. Crowd-funding can be implemented within these e-infrastructures, such as the one being developed within the UBORA project [9] (<http://ubora-biomedical.org>), together with other sponsorship options, including patrons funding specific projects or public/private organisms 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.

### **3) 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 and counting with the best possible professionals, which will be those more 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 be also granted and encouraged. Recent technological advances and paradigms, including social networks for collaborative learning and massive open online courses, may support this issue and help us to train a new generation of biomedical engineers capable of creating scientific-technological advances beyond the state-of-the-art and skilled for mentoring these progresses 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 will turn out to influence programmes of study worldwide, to which issues linked to collaborative design of open-source biomedical devices will be included.

#### **4) Harmonization of medical devices directives and accessible standards**

Constructing a framework for enabling medical technologies reach everyone and everywhere relies on the use of common design practices and on the fulfillment of broadly accepted regulations that must warrant patients' safety and that should allow for a compliant device to be commercialized and applied worldwide. Consequently efforts aimed at the global harmonization of regulations, which should also take account of the particular aspects present in collaboratively developed devices, constitute additional keys for success. In fact collaboratively developed projects may well result in safer devices if the correct principles are followed [9]. In addition, if we pursue a democratization of technologies, the concept of standards, which support designers in the development of compliant devices, should be reformulated and made widely available, even for free, as the compliance with regulations is compulsory and paying for access to standards prevents equality of opportunity. Ideally, standards should be concentrated on patients' safety and motivate designers to find more creative solutions, while helping them in the design process of effective devices. However, the truth is that large multinationals and their lobbies influence the development of standards for turning them into barriers of entrance against 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 [14].

#### **5) 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 the production, testing, commercialization and operation. For transforming collaborative design into collaboration through the whole life-cycle, the 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), 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**

Assuming the proposed call for action and its urgency, we propose the following immediate actions, as a way of setting the foundations for rebuilding medical technology and for walking towards the mid- and long-term objective:

- 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 (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 ABEM (the African Biomedical Engineering Mobility), 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 the International Conferences on Collaborative & Open Source Biomedical Engineering, but also opting for open-access publication of progresses 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 issues with a balance between pragmatism and idealism (*pedes in terra ad sidera visus*).

Quoting Saint Exupèry: "Our task is not to foresee the future, but to enable it".

***Let's work together for transforming the biomedical engineering field, towards the democratization of medical technology, as a key for achieving universal health care!***

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