THE UBORA PROJECT: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education

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ABSTRACT

The EU funded UBORA project aims at creating an e-Infrastructure, UBORA, for open source co-design of new solutions to face the current and future healthcare challenges of Europe and Africa, by exploiting networking, knowledge on rapid prototyping of new ideas and sharing of safety criteria and performance data. The e-Infrastructure is being implemented to foster advances in education and the development of innovative solutions in Biomedical Engineering, both of which are flywheels for emerging and developed economies. Through the UBORA e-Infrastructure, the biomedical community can generate and share open data and blueprints of biomedical devices, accompanied by the required procedures for respecting quality assurance, and assessing performance and safety. When properly implemented, as guaranteed by authorized Notified Bodies, these biomedical devices can safely be used in hospitals and on patients.

UBORA ("excellence" in Swahili) brings together European and African Universities and their associated technological hubs (supporting biomedical prototyping laboratories and incubators), national and international policymakers and committed and credible stakeholders propelled by a series of summer schools and competitions.

The teaching-learning experiences within the UBORA project, represented by summer schools and competitions, are being implemented on the basis of the CDIO (conceive-design-implement-operate) principles linking European and African students sharing the complete development process of innovative medical devices for global health concerns. Such collaborative open design teaching-learning experiences are expected to promote and rethink Biomedical Engineering Education across Europe, Africa and throughout the globe, while also serving as main initial input for making the UBORA e-Infrastructure become a key resource for the future of personalized and universal healthcare. In this study we present the overall strategy and the initial steps of the UBORA e-Infrastructure and related CDIO experiences.

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KEYWORDS: CDIO implementation, Case studies & best practices, Integrated learning experiences, Active learning. (Standards: 1, 3, 7, 8).

INTRODUCTION

Times are changing in the Biomedical Engineering field and the related teaching-learning activities, aimed at preparing students worldwide for the future of medicine and medical technology, should consequently adapt to these new times. Last decades have seen an exponential growth in the use of medical imaging technologies, not just for diagnostic purposes, but also as input for the personalized development of medical devices, using the adequate supporting software. Computer-aided design and engineering resources have become key tools for the design and *in silico* assessment of the performance of innovative biomedical devices. Rapid and automated manufacturing technologies, in many cases working following additive procedures (3D printing and bioprinting) are able to mimic the complex geometries of the human organism and to manufacture biomedical devices taking account of such complexity, sometimes even using biological living materials, for improved performance. Advances in robotics have enabled the development of minimally invasive surgical tools, which benefit also from remote operation and promote operation precision and patient speed of recovery. Above all, there is now a recognition of the relevance of collaboration between experts from different fields, including physicians, biologists, engineers, psychologists and even politicians, for the straightforward development of successful innovative medical devices (Díaz Lantada, 2013, 2016).

All these advances place mankind in a reasonably good position for facing global health concerns and for rapidly adapting to the consequences of population explosion, to the implications of an ageing global society and to the dangers of disease outbreaks; all this surrounded by environmental changes and political instability, which make of position more vulnerable. There is place for optimism but there is still a long way to go until these scientific-technological advances constitute a real global change. First of all, universal health care is far from being a reality, not just in developing countries (in fact all countries are developing according to the Sustainable Development Goals of the United Nations), but also in many countries with relevant economic power, including the United States and China, to cite just a couple of examples. In addition, medical devices and technologies are still mainly developed by making the economical aspects prevail over the social ones, which leaves people suffering from rare diseases helpless, as it is not profitable to invest in their being solved. A very similar situation is suffered by those without the support of a public health care and without the economic background for contracting a private insurance.

It is our responsibility, as educators and researchers in this field, to explain and demonstrate with inspiring experiences that other socially and economically successful models are possible, towards solving global health concerns and towards making these solutions accessible to all. Pioneering experiences have highlighted that the key for success relies on linking academic excellence, with innovation promotion strategies and open-source collaborative design methodologies (De Maria, 2014, 2015), all of which also connects with approaches trying to promote “engineering education for all” (Díaz Lantada, 2016). The relevance of e-infrastructures in our globalized economy and especially in development projects, in which collaborative tasks must be carried out by actors working in different regions or countries applying their specific expertise for fulfilling the planned objectives, is also to be taken into account (Spyridonis, 2015), as happens with the possibilities provided by open-access software resources. Furthermore, well established university digital fabrication labs or “fab-labs” may also play a relevant role for the universalization of health care and for the future of mass-personalization in the medical field, if open-access schemes are promoted. Finally, open-access teaching resources and training opportunities are also

fundamental for counting with the more talented and motivated students, regardless of their social status, race, religion, political opinions, sex or sexual orientation.

Towards the aforementioned academic excellence and pursuing the integration of all the stakeholders, participants, decisions and technologies present in the development of any medical product, we believe that applying the CDIO (Conceive-Design-Implement-Operate) methodology (Crawley, 2007) constitutes a very adequate approach. In this study we present the initial stages of the **"UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education"** project, an EU funded research and innovation project pursuing a reinvention of Biomedical Engineering by means of innovative collaborative design strategies and educational activities in a global context. The project is described further on, before entering into details regarding the educational aspects of our proposal.

THE UBORA PROJECT

The EU funded UBORA project (*H2020-INFRASUPP-2016-2017 call: Support to policy and international cooperation*) aims at creating an e-Infrastructure, UBORA, for open source co-design of new solutions to face the current and future healthcare challenges of Europe and Africa, by exploiting networking, knowledge on rapid prototyping of new ideas and sharing of safety criteria and performance data. The e-Infrastructure is being implemented to foster advances in education and the development of innovative solutions in Biomedical Engineering, both of which are flywheels for emerging and developed economies. It is conceived as a virtual platform for generating, exchanging, improving and implementing creative ideas in Biomedical Engineering underpinned by a solid safety assessment framework. Besides the provision of resources with designs, blueprints and support on safety assessment and harmonization, specific sections for needs identification, project management, repositories and fund raising are also foreseen.

UBORA ("excellence" in Swahili) brings together European and African Universities and their associated technological hubs (supporting biomedical prototyping laboratories and incubators), national and international policymakers and committed and credible stakeholders propelled by a series of summer schools and competitions. Through the UBORA e-Infrastructure, the biomedical community can generate and share open data and blueprints of biomedical devices, accompanied by the required procedures for respecting quality assurance, and assessing performance and safety. When properly implemented, as guaranteed by authorized Notified Bodies, these biomedical devices can safely be used in hospitals and on patients. In a nutshell, UBORA couples the open design philosophy with Europe's leadership in quality control and safety assurance, guaranteeing better health and new opportunities for growth and innovation.

The teaching-learning experiences within the UBORA project, mainly summer schools and competitions, are being implemented on the basis of the CDIO (conceive-design-implement-operate) principles linking European and African students sharing the complete development process of innovative medical devices for global health concerns. Such collaborative open design teaching-learning experiences are expected to promote and rethink Biomedical Engineering Education across Europe, Africa and throughout the globe, while also serving as main initial input for making the UBORA e-Infrastructure become a key resource for the future of personalized and universal healthcare.

We believe that the approach is quite innovative, especially regarding the open-access strategy and the collaborative design approach, all of which, when connected with the CDIO methodology, may prove a relevant breakthrough in the Biomedical Engineering and

Biomedical Education fields. Main objectives of UBORA and their relationship with the United Nations' Global Goals are schematized in Figure 1.

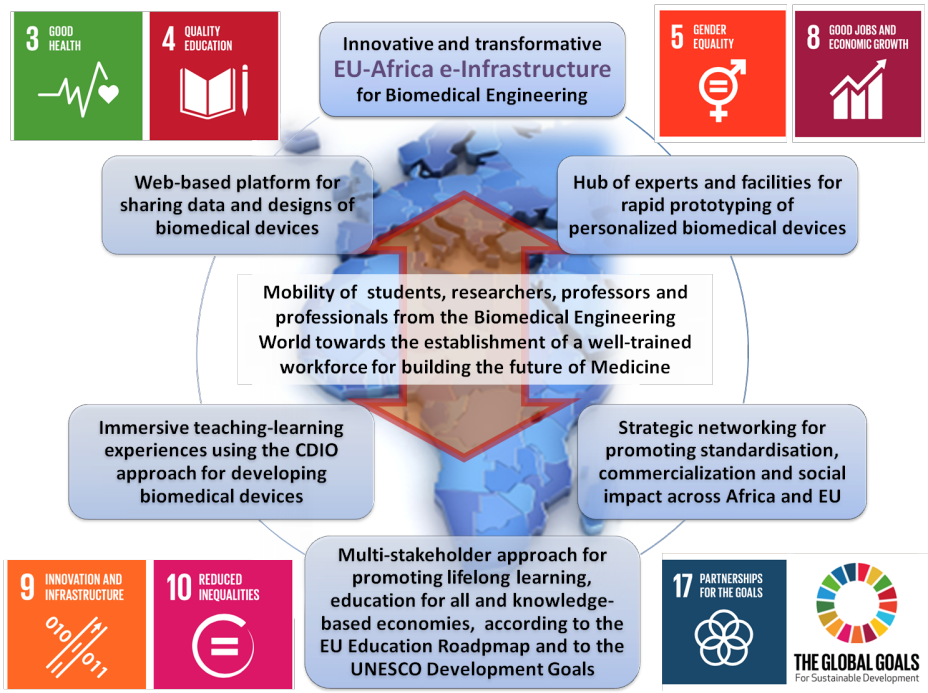

Figure 1. UBORA's objectives and connection to the United Nations' Global Goals.

Regarding project organization, UBORA is structured according to the development timeline shown in Figure 2. It is important to note that in parallel to the development of the e-infrastructure, in fact a collaborative platform for the development of biomedical products, the summer schools are being organized. We have planned a summer school in Africa (for October 2017) centered in the "maternity and early childhood" topic and a summer school in Europe (for September/October 2018) focused on the topic of "ageing". Participation in the summer schools is to be granted to the students among the participant universities that detect the more relevant medical needs and present the best product ideas for addressing such needs. The selected needs-products will be developed following a complete CDIO approach during the summer schools and subsequent months. Next section covers the planning of the summer schools, details the learning objectives and expected outcomes, while also dealing about the main challenges and implementation proposals for reaching a complete CDIO cycle in the framework of summer schools, which is demanding.

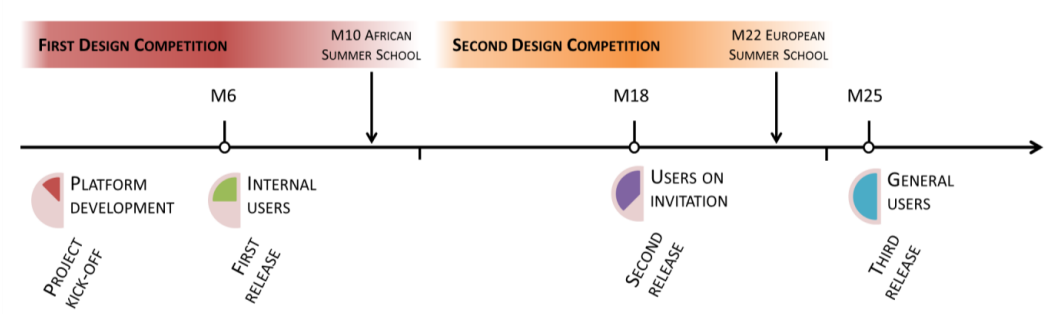

Figure 2. UBORA development timeline. Different releases of the e-infrastructure with increasing participation of users in parallel to the development of educational activities.

CDIO APPLIED TO SUMMER SCHOOLS AND BIOMEDICAL PRODUCT DEVELOPMENT

Planning of the summer schools

Summer schools are planned in advance, with an initial competition or "call for ideas" linked to innovative medical devices in the contexts of "maternity and early childhood" and "ageing society", depending on the summer school and year. The participants of the competition will be assessed and, each year, the best 20-25 ideas and students will be selected for participation in the summer school. The concepts will be discussed via email by students and professors, so as to help students arrive at the summer school with a clear concept for further development. According to the distribution of activities of the summer schools, shown in Table 1, students will just have 5 days for materializing their ideas. After conceptual discussions, a final selection of 5-6 devices, to design and develop during the summer school, will be made and groups of 4-5 students will be formed to carry out the developments.

Context and contents, learning objectives

The summer schools aim at providing students with a clear overview of the whole life cycle of a medical device, from the conceptual and planning stages, through the design and implementation, towards the operation and life, in compliance with CDIO standard 1. This will be achieved by a combination of experts' lessons, cases of study and CDIO teamwork activities. Lessons will cover aspects such as: introduction to the medical industry, global healthcare issues, methodologies for the development of biodevices, product planning, safety issues and standardization, creativity promotion, conceptual design, materials selection strategies, advanced design and manufacturing resources, production and commercialization, and future trends in biomedical engineering. Different cases of study linked to real developments will help to illustrate these methodologies and will serve as examples for the teamwork activities. Teamwork CDIO sessions will consist of students working upon their concepts trying to reach a final safe design and, depending on the complexity of the device, a prototype for testing within the summer school or along the following weeks, in compliance with CDIO standard 3, 7 and 8. Students' assessment will consider if the device fulfills a real relevant need, if the design process has been methodically performed, if creativity promotion tools have been adequately employed and if the team was worked successfully to achieve a reliable design. The different developments will serve as cases of study for future participants and will be uploaded as teaching resources to the UBORA platform. The experts' lessons and available cases of study will be also placed in the platform and videos will be recorded with the idea of achieving in the near future a massive open online course (MOOC) as introduction to the medical industry and to medical device development strategies.

International summer schools focused on medical device development				
Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**
Expert's lesson 1	Expert's lesson 3	Expert's lesson 5	Expert's lesson 7	Expert's lesson 9
Expert's lesson 2	Expert's lesson 4	Expert's lesson 6	Expert's lesson 8	Expert's lesson 10
Coffee pause				
Case study 1	Case study 3	Case study 5	Case study 7	Case study 9
Case study 2	Case study 4	Case study 6	Case study 8	Case study 10
Lunch				
Teamwork	Teamwork	Teamwork	Teamwork	Teamwork
Teamwork	Teamwork	Teamwork	Teamwork	Teamwork
Tea pause				
Teamwork	Teamwork	Teamwork	Teamwork	Final assessment & awards
Discussion	Discussion	Discussion	Discussion	
Dinner and talk				End party

Table 1. Distribution of activities for the summer schools.

TECHNOLOGIES FOR THE PROMOTION OF OPEN BIOMEDICAL ENGINEERING: RELEVANCE AND POTENTIAL IMPACT FOR COLLABORATIVE CDIO EXPERIENCES

Apart from the personal implication and experience of the partners, some technological issues make the UBORA project special for the future of medical engineering and technology, including the use of e-platforms for project management and collaborative design (in fact UBORA will be such a collaborative platform), the guiding role of EU regulation and ISO standards, the combined use of computer-aided design & engineering resources, together with rapid prototyping technologies, the employment of open-access repositories of 3D geometries and options for crowd-funding and sponsorship, as detailed below.

e-Platforms for project management and collaborative design of safe biodevices

The future of medical device development will surely rely on close collaboration among the main stakeholders, including patients, patient associations, healthcare professionals, designers, engineers, psychologists and even normal citizens, along the whole life cycle. The fact is that global health concerns may need to be addressed very differently depending of the social, economical and environmental contexts, in which a specific device performs its tasks. A device working fine in a mild-climate country may not perform equally in a cold winter, an implant placed in a patient living in a city may be more easily overviewed than when working with patients in remote locations, where additional logistical and maintenance issues arise, to cite just a couple of examples that put forward the need to collaborate for the development of successful biodevices. The collaborative approach brings into the design phase also an intrinsic revision process, driven by a virtual community, composed of a heterogeneous and large population (from highly skilled designers to stakeholders), which has become an active player, and no longer a passive element. This community is the best analyst in terms of quality, reliability and feasibility. Couple to this internal check, UBORA will pursuit the mandatory use of Medical Device Regulation as point of reference for ensuring patients, operators and environment safety. Platforms for collaborative design, such as the one we are developing within the UBORA project, may constitute a turning point in the way biodevices are developed and in the way problems are found and solved, which is also linked to the promotion of personalization in medicine.

"Fab-labs" and 3D printing hubs

In the case of the UBORA project, all partners will support students and the projects developed within the summer schools with their manufacturing facilities, which include: fused-deposition modeling printers, 3D bioprinters, laser stereolithography, CNC machining, PDMS mold making and rapid mold manufacture for pre-production analyses, among other tools. It is important to highlight, that the possibility of prototyping and, consequently, being able to complete the full CDIO cycle, from the concept, to the validated prototype, constitutes an extra source of motivation for students taking part in these highly-rewarding teaching-learning activities. In addition, the UBORA e-platform will be also a meeting point for product development labs with interest in the biomedical field worldwide. The network of fab-labs and printing hubs will support not only teaching-learning tasks, but also the manufacture of prototypes for testing of the biodevices under development, linked to pre-commercial test for safety clearance.

Crowd-funding and impact promotion e-platforms

Again, the use of collaborative e-platforms may be 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 way. Crowd-funding can be implemented within platforms such as the one from the UBORA project, 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 resources will be also explored and may constitute and additional breakthrough in the medical field towards the democratization of medical technology.

RETHINKING STUDENT MOBILITY SCHEMES WORLDWIDE: RELEVANCE AND POTENTIAL IMPACT OF THE CDIO APPROACH

Another relevant aspect of the UBORA project and the related already mentioned teaching-learning tasks, especially the planned summer schools, is connected to the promotion of student mobility and to the search for novel ways or schemes for enabling student mobility and collaboration among professors worldwide. In our opinion, more flexible mobility schemes are needed, which can be adapted to the needs and dreams of our students, with the adequate formative rigor and institutional support, but without too complex bureaucratic frameworks, which prevent real mobility in a global context.

The UBORA e-platform can also serve to motivate mobility among partners and to fund it by means of sponsored scholarships. In fact, the attendance to the summer schools will be funded by the UBORA project for those students who present the best project ideas in the preliminary design competition. The sustainability of the e-platform will depend on the quality of teaching-learning experiences we may develop and on the reliability of the designed medical devices. All this may let us call the attention of larger organizations, sponsors and patrons for further addressing medical needs and transforming Biomedical Engineering Education worldwide.

We expect that, as a consequence of the CDIO activities we are preparing for the EU-African summer schools, the different universities taking part in the UBORA project will progressively incorporate the "conceive – design – implement – operate" approach to their engineering programmes and consider joining the International CDIO Initiative. This would help us to promote long-term collaborations and to implement additional mobility schemes, not just bilaterally among the partners, but possibly as multi-university multi-degree programmes, starting with the Biomedical Engineering field. We hope to collaborate further on with other partners from the International CDIO Initiative, as the UBORA e-platform is open for collaboration to all persons with the will to work for more personalized and accessible medical technologies, with bottom-up strategies for solving the problems of people needing support.

CONCLUSIONS

We have presented the initial stages of the **"UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education"** project, an EU funded research and innovation project pursuing a reinvention of Biomedical Engineering by means of innovative collaborative design strategies, with a very relevant focus on safety and intrinsically safe design, and educational activities in a global context. The main objectives of the project have been described and special attention has been paid to the planning of summer schools based on teamwork CDIO activities linked to real development projects of innovative medical devices.

The proposed summer schools try to achieve an equilibrium between theory (experts' lessons) and practice (case studies and CDIO projects), so as to introduce students to the complex issues that arise in the development of medical devices. The described summer schools constitute initial teaching-learning activities linked to the development of the UBORA e-platform, which we hope will transform innovation in Biomedical Engineering, by means of the promotion of additional educational activities, including MOOCs, student mobility and joint degrees, among others; and by placing in contact patients, clinicians and researchers, from different context and backgrounds, for the collaborative design of the medical devices of the future.

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BIOGRAPHICAL INFORMATION

Arti Ahluwalia is Professor of Bioengineering at the Department of Ingegneria dell'Informazione, University of Pisa, and affiliated with the Research Center "E. Piaggio", where she is head of the IVM Group (www.centropiaggio.unipi.it). Prof Ahluwalia is also an associate of the National Council of Research Institute of Clinical Physiology (CNR-IFC), and head of the NanoBioscopy Lab. She has several papers published in international scientific journals (over 100) and is author of 13 patents on microfabrication, and on micro-fabricated multi-compartmental bioreactors. She is co-founder of two high-technology companies and 5 of her patents have been industrialized to date. She coordinated an EU-Asialink project on the development of human resources in biomedical engineering in South East Asia. She has pioneered Open Education in Biomedical Engineering in Africa and is a Scientific and Education Consultant for Biomedical Engineering for the United Nations Economic Commission for Africa (UNECA). She was instrumental in setting up the African Biomedical Engineering Consortium (ABEC) and is the consortium's Patron, and the coordinator of UBORA EU project.

Carmelo De Maria is Assistant Professor of Bioengineering at the Department of Ingegneria dell'Informazione, University of Pisa, and affiliated with the Research Center "E. Piaggio". He is guest professor in bioengineering at Addis Ababa University, and member of the African Biomedical Engineering Consortium secretariat. His research interests are in the field of additive manufacturing/rapid prototyping technologies, with a particular focus in Biofabrication. He has several papers published in international scientific journals (over 30) and in 2016 he received the 1st award as Young Investigator from the International Society for Biofabrication. De Maria is also co-founder and president of the FabLab Pisa.

Andrés Díaz Lantada is Professor in the Department of Mechanical Engineering at ETSI Industriales – UPM. His research activities are aimed at the development of biodevices using modern design, modeling and manufacturing technologies and he incorporates these results to subjects linked to product development. He is Editorial Board Member of the International Journal of Engineering Education and CDIO contact at UPM. He has received the "TU Madrid Young Researcher Award" and the "TU Madrid Teaching Innovation Award" in 2014 and the "Medal of the Spanish Academy of Engineering to Young Researchers" in 2015.

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Philippa Ngaju Makobore is an Electrical Engineer and is currently the Department Head of the Instrumentation Division at the Uganda Industrial Research Institute (UIRI). Her team comprises of electrical and computer engineers that design and develop electronic applications for Healthcare, Agriculture and Energy. To date the Division's portfolio has over 7 projects, which she supervises, with 3 medical device prototypes in their advanced stages. These projects have won both international and local awards including a 1st place Innovation Award at the 2016 World Patient Safety, Science and Technology Summit.

June Madete is a Biomedical Engineer specializing in biomechanics, a researcher and senior lecturer at Kenyatta University with special interest and expertise in collections, analysis and interpretation of gait data using various motion analysis software and hardware. Her research involves combination of these techniques with animal research in the field of euro science, video fluoroscopy, x-ray and CT data. In 2011-2012, she did a study that looked at a specific group of patients who underwent total knee replacement, the study aimed at understanding the relationship between surgical accuracy and joint function. She seeks to develop biomechanics within Kenya.

Albo Aabloo is Professor at the Institute of Technology at Tartu University. He is the leader of the intelligent materials and systems lab and has background in mathematical modelling, material science and robotics, as well as experience in several international projects and collaborations with industry.

Arni Leibovits is currently obtaining a Master of Business Information Technology in Tallinn University of Technology. He holds a Bachelor's degree of Information Technology from the University of Tartu. His work experience includes working as software developer at Nortal Inc. (2001–2007). He is Co-Founder, Software Craftsman and Board Member at AgileWorks Ltd.

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