

THE “UBORA” DESIGN COMPETITION: AN INTERNATIONAL STUDENT CHALLENGE FOCUSED ON INNOVATIVE MEDICAL DEVICES DEVELOPED USING THE “CDIO” METHODOLOGY

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ABSTRACT

UBORA is an educational and design online platform or infrastructure aimed at the collaborative development of open-source medical devices (OSMD) to address current and future global healthcare challenges. It pretends to support the healthcare professionals and the medical industry with new methods for creation of innovative solutions that take into account needs, safety, feasibility, efficacy and performance. To support the implementation and testing of the UBORA e-infrastructure and to promote the future impact of OSMD, teaching-learning actuations play a fundamental role. In consequence, in parallel to the implementation of the mentioned infrastructure, a set of international design competitions and schools are being developed. In this study we present the results from the “First UBORA Design Competition”.

This “First UBORA Design Competition” counted with a total of 113 submitted projects, from which 60 were selected for a second round. After such second round, 26 especially relevant projects and their teams, which lived in many cases a complete CDIO experience, have been assessed and chosen as finalists. Among presented projects and solutions we can cite: medical devices for detecting or preventing malaria, portable vaccine coolers, systems for the sterilization of medical and instruments, incubators for newborns, devices for monitoring pregnancy, breast pumps with cooling and preservation systems, 4D printed ergonomic supports, polymeric devices for treating articular pathologies and CPAP devices for babies, to mention just a few examples. Most of the finalist teams have reached the prototyping and testing stage, following the recommendations provided by the organizers of the competition and by the participating mentors, in order to better answer the questions from the two-stage evaluation sheets, which serve as a sort of “lean canvas” or creativity promotion templates to guide the development process. The first stage of the competition mainly covered the conceptual stage and the second stage focused on the design, implementation and operation of the obtained prototypes. The international magnitude of the competition can be appreciated by taking into account that teams from 15 universities and 12 countries from Europe and Africa took part in this first edition. Main benefits, lessons learned and future challenges, linked to these international medical device design competitions, are analyzed,

taking account of the available results from this first implementation during 2017, so as to improve towards the future editions.

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KEYWORDS

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

INTRODUCTION

Student competitions can constitute excellent teaching-learning experiences because they tend to promote student motivation, which is arguably the most relevant key to success in Engineering Education. In many cases competitions serve to approach students to their professional practice, let them apply basic scientific-technological knowledge to real life problems, promote their teamwork and communication skills and even involve them in multi-cultural international contexts, while letting them escape from their routine for some hours or days, which is always beneficial.

However, there are relevant challenges linked to the implementation of really formative student competitions and connected with their long-term sustainability. First of all, in many cases competitions are organized by students themselves or by student associations, which normally limits their temporal sustainability due to the short life-cycle of many student associations. Apart from that, students do not usually focus on the development of adequate assessment methods for their competitions, as objective procedures are not so easy to implement. Secondly, in other cases, competitions are organized by enterprises looking for innovative solutions for their own interests or as a way of finding or attracting talent, which again can limit their sustainability, as the entrepreneurial objectives can vary easily in the short-term. In these cases, assessment is usually not performed in ideal conditions either, as these entrepreneurial competitions are typically overviewed by the human resources departments, whose understanding about engineering (and teaching) is not always as desired. Finally, student competitions are normally performed as extra-curricular activities, with no connection to the plans of study and with no intention of becoming part of these plans either, which leads sometimes to curricular and temporal mismatches (i.e. competitions organized in exams period, topics without interest for the participants...).

Counting with the active support of professors for the conception, implementation and evaluation of student competitions can prove very positive for adding value to the formative and transformative potential of student competitions, as connected with the enhancement of teaching-learning objectives, with the performance of an adequate evaluation and with the search for a long-term sustainability, possibly connected with the consideration of these contests as curricular activities. Applying the CDIO approach (Crawley, 2007 & CDIO Standards) to student contests, letting students live through complete conceive-design-implement-operate cycles linked to real engineering systems, can constitute also a relevant driver of change. Some exemplary proposals have been able to create long-term and international competition schemes with students living complete CDIO cycles, in which engineering systems as complex as competition cars and solar houses have been

implemented: The Formula SAE (running since 1980) and the Solar Decathlon (starting in 2002) are some of the more relevant examples of student competitions, which started with the support of US universities or US governmental departments, counting with relevant involvement of professors since the beginning, and are now truly international events. The engineering systems developed within these competitions are complex and provide students with holistic engineering design experiences. Other engineering systems common from engineering design competitions include: motorbikes, drones, ultra light planes, among others.

In our case, conscious about the relevance of equitable medical technology for the future of global health coverage and compromised with the development and teaching of open-source approaches for the development of biomedical products (De Maria, 2014, 2015), we have conceived and developed an international student competition focused on the complete development of innovative medical devices, which is presented in this study.

THE “UBORA” PROJECT

The EU funded UBORA project (*H2020-INFRA-SUPP-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 (Ahluwalia, 2017). 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.

In this work, we present the results from the first UBORA Design Competition (2017), which is also the first in a series of international biomedical device design competitions focusing on open innovation and collaborative design approaches and devoted to the conception, design, implementation and operation of biomedical devices. In turn, these UBORA Design Competitions give access to the UBORA Design Schools, as one member per finalist team of these design competitions receives funding to attend the mentioned UBORA Design Schools (also presented in this 14th International CDIO Conference of Kanazawa). The teaching-learning objectives of the competition, its development stages, the main results of the first implementation and the more relevant future challenges are presented in the following pages.

ENGINEERING COMPETITION FOLLOWING A COMPLETE “CDIO” CYCLE: THE FIRST “UBORA” BIOMEDICAL DEVICE DESIGN COMPETITION

Objectives

The main objective of the UBORA Design Competitions was letting groups of students live through a complete CDIO process, linked to the development of innovative biomedical devices and performed in two stages, one for presenting the idea and one for focusing on design and prototyping aspects. Making them aware of the relevance of engineers for improving society and involving them in an international context in connection with relevant health issues, in accordance with Part 4 of the CDIO Syllabus, were also desired outcomes. The stages of the competition let students face relevant challenges typical from the biomedical industry, including: the finding of a socially relevant medical need, the specification of a biomedical device for solving such medical need, the analysis of existing solutions, the selection of medical device class or the development of a design oriented to production. For supporting students and gathering the necessary information to assess participants of the competition, two working sheets with different sections were implemented, one as final deliverable of the first stage and one as final deliverable of the second stage. These evaluation sheets served as a sort of “lean canvas” or creativity promotion templates to guide the development process. It is important to note that the topic of this first UBORA Design Competition was child and maternal health and that the final award for each finalist team was a travel fellowship, for one team member, to attend the first UBORA Design School of 2017.

First stage

The first UBORA Design competition was launched at the beginning of 2017 and open to bachelor's and master's degree students from the institutions of the UBORA consortium (University of Pisa, Universidad Politécnica de Madrid, KTH, Kenyatta University, UIRI and University of Tartu) and from the African Biomedical Engineering Consortium (ABEC). A total of 15 institutions from 12 countries across Europe and Africa were called for participation. During the first stage we received 113 submissions, which conceptually described medical devices for solving relevant medical issues, also analyzing their potential impacts socio-economic impacts. Figure 1 shows some of the filled in templates received, which contain the basic information of the conceptual stage. A total of 60 teams were selected for the second

round, assessed on the basis of: health impact (5 points) and innovation (5 points). Aspects including the focus on child mortality, the addressing of the health need, the demonstration of potential impact, the proposal of creative solution, the rationale for the unique approach and a search for cost efficient technical were considered (see <http://ubora-biomedical.org>).

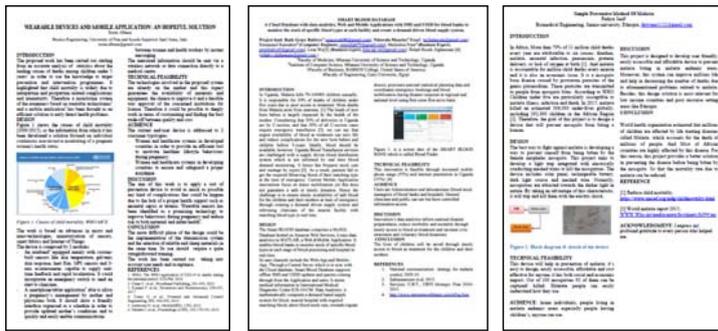


Figure 1. Examples of first stage submission documents: Abstracts describing the medical need and common issues, together with the proposed medical device concept.

Second stage

During the second stage 60 complete submissions were received, from which a total of 26 finalist teams was selected. The templates used to gather the required information during the first and second stages can be found at: <http://ubora-biomedical.org>. The second stage focused on more specific design, production and supply chain related aspects, including analyses on how to reach local populations in remote places or even involve them in the development or personalization processes. Figure 2 shows some examples of implemented prototypes during this second stage, which was evaluated again according to health impact and innovation, but taking also into account the degree of completion of the whole CDIO cycle achieved by the teams.

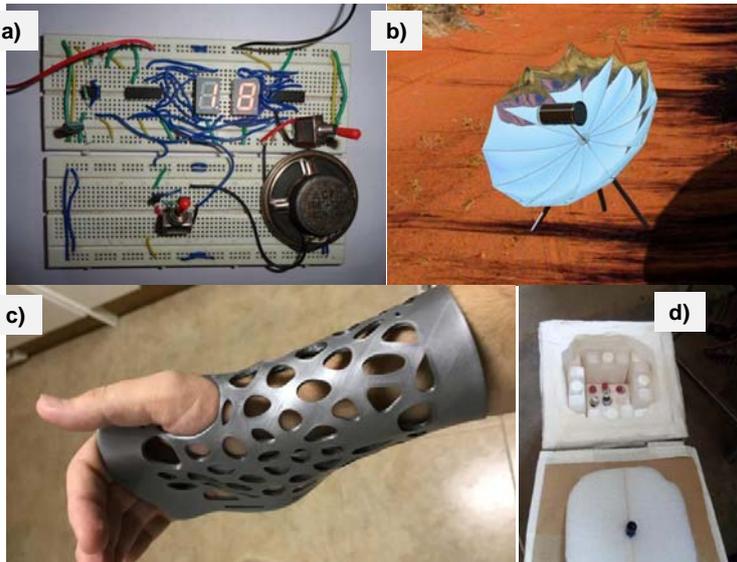


Figure 2. Examples of implemented prototypes during the second stage of the competition: a) Electronic board for monitoring baby temperature (with audio alert). b) Low-cost solar autoclave. c) 4D printed splint for articular pathologies. d) Vaccine cooler with temperature sensor for improved traceability of the cold chain.

Main results and future challenges

CDIO approach was supported by means of guiding documents, which helped students to specify and describe their concepts, in the first stage, and to address relevant engineering aspects and present their final solutions, in the second stage. Professors from the involved institutions acted as supporting mentors, either *in situ* or by means of online interactions. Regarding participation, a total of 113 projects from undergraduate student teams from 10 ABEC and 4 UBORA universities were received (Figure 3a). Overall, we had 334 students, 253 from ABEC and 81 from UBORA member institutions. Sixty (60) projects were selected for the second round. After the first stage review, 57 projects were submitted (Figure 3b) and of these, the first 26 were selected as winners. A total of 191 students participated (133 from ABEC, 58 from UBORA). One student from each team received funding for travel and accommodation to participate in the Design School (see our partner document presented also at the 14th International CDIO Conference about the UBORA Design School).

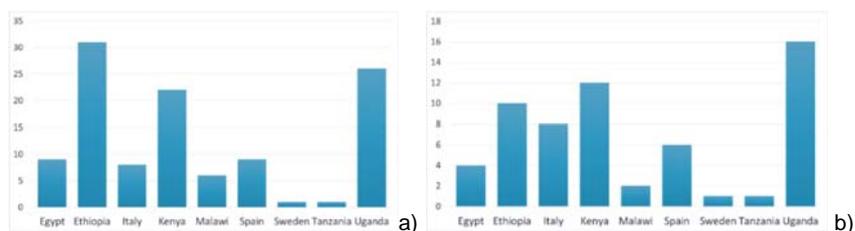


Figure 3. Number of projects submitted per country in the first (a) and second stage (b).

Among the biomedical devices presented, all of which were centered on infant and child mortality and health we can cite: medical devices for detecting or preventing malaria, portable vaccine coolers, systems for the sterilization of medical and instruments, incubators for newborns, devices for monitoring pregnancy, breast pumps with milk cooling systems, 4D printed ergonomic supports, polymeric devices for articular pathologies and CPAP devices for babies, devices for filtering water, to mention just a few examples. All of the finalist teams addressed relevant health concerns and provided innovative concepts and basic designs. Most of the finalist teams reached a basic prototyping and testing stage, following the recommendations provided by the organizers of the competition, in order to better answer the questions from the two-stage evaluation sheets and to validate their concepts and designs. At least one member of each finalist team attended the first UBORA Design School of Nairobi (December 2017), in accordance with the received awards, which constitutes a very special selection for such design schools based on merit.

The experience resulted satisfactory both for students and teachers, as can be seen from their active involvement as members of the UBORA community after the end of the competition (). Currently the second UBORA Design Competition is being performed, which will end with a selection of participants for the second UBORA Design School (to be performed in Pisa, in September 2018). Regarding future challenges, we would like to focus on the sustainability of these international teaching-learning activities and to see them become part of worldwide actuations linked to establishing a new generation of biomedical engineers focusing on open-source approaches towards equitable access to medical technologies. Finding sponsors and linking these actuations with curricular activities of plans of study of the participant universities may be fundamental, as happens also with the potential incorporation of our partners to the international CDIO initiative.

CONCLUSIONS

We have presented the implementation process and main results of the first UBORA Design Competition, an international contest, with participation of students from the partners of the UBORA and ABEC consortia, in which teams of students live through the complete development process of innovative medical devices. These developments have followed the CDIO approach and have been implemented in two phases, one linked to the more conceptual aspects, the second one connected to design and prototyping activities. A total of 113 teams from 12 European and African countries and 15 universities have taken place in this competition and a total of 24 finalist teams have been granted access to the first UBORA Design School, a complete CDIO experience linked to biomedical devices in just one week, which is also presented in this 14th International CDIO Conference. To our knowledge, this

competition provides one of the very first examples of CDIO-related contests applied to medical technology worldwide.

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SAE Formula Competition: <https://www.fsaeonline.com>

Solar Decathlon Competition: <https://www.solardecathlon.gov>

United Nations. Sustainable Development Goals: 17 Goals to transform our World:

<http://www.un.org/sustainabledevelopment/sustainable-development-goals/>

Regarding the UBORA Project, additional information and developments can be found at:

UBORA Project: <http://ubora-biomedical.org>

UBORA e-Infrastructure: <http://ubora-kahawa.azurewebsites.net> (preliminar versión).

Second UBORA Design Competition: <http://ubora-biomedical.org/design-competition-2018/>

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 hi-tec 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. She was instrumental in setting up the African Biomedical Engineering Consortium and is the consortium's patron, and the coordinator of the UBORA EU project.

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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 and manufacturing technologies. 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.

Licia Di Pietro is a PhD Biomedical Engineering Student at Research Centre E. Piaggio of University of Pisa, Italy. She received the Bachelor's and Master's Degrees in Biomedical Engineering from University of Pisa in 2014 and 2017 respectively. Her research interests include Global Health with particular attention to developing countries. She is working on manufacturing of open-source and low cost medical devices, compliant with the international standards.

Alice Ravizza is regulatory consultant and R&D reviewer for medical devices, expert in implementation of Good Manufacturing Procedure and Quality Management System (ISO 13485). Dr. Ravizza is involved in several CE marking processes linked to class I, II and III medical devices. She performs courses on medical regulation and supports the UBORA project with her expertise in safety and quality promotion.

Mannan Mridha is a Senior Researcher at KTH (Royal Institute of Technology) in Stockholm. With merit scholarships acquired M.Sc. Eng. degree from Warsaw Technical University, Ph.D. and M.Ed. degree from Linköping University in Sweden. He has working experience with teaching and research in BME at the University of Linköping, KTH, University of Oxford and

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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. Her multidisciplinary team designs and develops electronic applications for Healthcare, Agriculture and Energy. To date the Division's portfolio has over 7 projects, which she supervises. These projects have won several 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 analysis and interpretation of gait data using various analysis software and hardware. Her research involves combination of these techniques with animal research in the field of video fluoroscopy, X-ray and CT data. She seeks to develop biomechanics within Kenya.

Janno Torop works at the Institute of Technology at the University of Tartu developing research in the field of Materials Chemistry and Nanotechnology, in connection with the development of smart materials, structures and actuators. He supports UBORA as mentor of project-based learning activities and as developer of biomedical devices.

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