Improving African Healthcare through Open Source Biomedical Engineering

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Abstract—**The lack of accessible quality healthcare is one of the biggest problems in Africa and other developing countries. This is not only due to the unavailability of resources, but also to the absence of a structured formative process for the design and management of healthcare facilities. Crucial to the effective and efficient exploitation of healthcare facilities and biomedical technology is the support of Biomedical engineers, who form the link between technology and medical practice. Indeed Biomedical engineers, together with nurses and doctors, form the pillars of healthcare systems in the developed world. In this paper, the Open Source for BioMedical Engineering (OS4BME) project and its kick off summer school are presented. The OS4BME project aims at developing a new generation of biomedical engineers, able to exploit emerging technologies generated by the recent "Makers" revolution. During the one week summer school, students from various sub-Saharan countries were introduced to these new design, development and sharing paradigms. Students worked together to identify new simple biomedical devices, which could help in daily clinical practice in their countries. A cheap and easy-to-use neonatal monitoring device was chosen as a Crowd design project. The OS4BME Baby Monitor was designed and assembled by the students during the one week summer school, demonstrating the creative potential of the new generation of biomedical engineers empowered with the paradigms of crowdsourcing and rapid prototyping.**

Keywords-Biomedical Engineering; Open Source; Open Hardware; Crowdsourcing; Africa.

I. Introduction

While the givers of healthcare are certainly doctors, clinicians and nurses, at least in the developed world, biomedical engineers are widely recognised as being the cornerstone of any medical facility with high technology diagnostic and therapeutic equipment and devices. In the less developed or emerging countries, the role of engineers in the hospital context is less well consolidated, as pointed out in our short paper presented at the VIII International Conference on Digital Society in 2014 [1].

Indeed, the scarcity of accessible quality healthcare in Africa is inextricably linked not only with the lack of resources, but also with the lack of adequately trained biomedical engineers [2]. Excluding South Africa, apart from few singular initiatives (in Nigeria and Ghana), no university in sub-Saharan Africa offers a fully-fledged Biomedical Engineering graduate and post-graduate programme [3].

Several reasons for this can be identified, but one of the most important is the absence of a clear common understanding of BioMedical Engineering (BME) as a field of study both in higher education as well as in the medical sector. Although there are a number of technical level clinical and biomedical engineering courses scattered through sub-Saharan Africa, their quality and content are often questionable [4]. Moreover, medical equipment does not have common standards or operating protocols; indeed in most developed countries, hospitals and clinics have very expensive maintenance contracts with manufacturers who train their own specialized technicians [3]. As a result, the medical device industry in Africa is largely absent and there is an over reliance on foreign companies to repair and design biomedical instrumentation, and resolve technical problems. Very often developed countries donate machines to African hospitals and clinics. While this is an honourable act, the machines usually end up being abandoned when they stop working due to lack of adequate maintenance [5] [6].

The experience of one of the authors in the *ASIALINK* project, "Development of Core Competencies in the areas of Biomedical and Clinical Engineering in the Philippines and Indonesia 2005-2008" [7] [8] has shown us that long term and sustainable improvements can only come through i) recognition on the part of policy makers, of the importance of in loco trained experts capable of managing and repairing biomedical equipment and ii) development of expert skills through individualized programmes that cater to the specific social, cultural and technological needs of a region. These are the two keys to a sustainable and efficient health care system.

However, the world has completely changed with respect to 2006, when the *ASIALINK* project was considered a landmark in South East Asia. The continuous connectivity with tablets, mobile phones, the rapid dissemination of social networks, and the access to free e-learning [9], makes teaching easier and harder at the same time, because of the huge amount of available information.

The world of BME is also changing, here again thanks to various virtual communities that live, exchange and discuss on the web. While, a couple of years ago, the development of biomedical devices was essentially linked to companies and universities, now the first examples of open source biomedical devices, such as the Gammasoft Open electrocardiogram and the Smartpulse oximeter are beginning to appear [10] [11]. Although these instruments are not accurate or safe enough to be inserted in the clinical routine, their use can probably save a life more than a damaged, unused (e.g., for high cost) or useless (e.g., because no one knows how to operate) Magnetic Resonance Imaging machine.

Indeed, as The Economist [12] points out in an insightful laymans overview of this burgeoning field, software-reliant devices have also brought on new types of potential risks for patients. The article underlines the difficulty of exposing specific problems with these products, given that medical software (and hardware) is proprietary and patent-protected, thus veiled in secrecy [13]. The open-source approach could, in theory, make it easier to fix, or even avoid, dangerous flaws before they hurt or kill hundreds or thousands of patients. Despite this virtual revolution the mainstream academic community in most countries, developed or not, remains largely ignorant of the potential of open source software, hardware and prototyping. This is particularly evident in Africa - we refer in this paper to sub-Saharan Africa excluding South Africa - where tradition and hierarchy play a strong role at all levels, more so in academia. The authors are of the opinion that academia, and specifically biomedical engineers in higher education, must embrace these new tools, and pass on the message that an Open Source product, developed by a community, without a multinational brand is not equal to un-reliable.

Indeed, today, thanks to crowdthinking and crowdsourcing, the design of several products has an intrinsic revision process, driven by the community, which has become an active player, and no longer a passive element. The community is the best analyst in terms of quality, reliability and feasibility. While this philosophy is now well accepted in the "software" world, there is still an unjustified unbelief in open "hardware", because many people are anchored to the consolidated production processes, in which product development is affected by high costs due to the inflexibility of high throughput fabrication technologies (e.g., injection molding). As described in the seminal work of Chris Anderson *"In the next industrial revolution, atoms are the new bits"* [14] [15] 3D printing (later described in the text) is giving everyone, companies, makers, and inventors, the tools that were the exclusive prerogative of a few companies less than ten years ago.

A note of caution however; the freedom given by the Web, and by the possibility to share, fork and re-implement projects, which characterises the Open Source Software, Electronic, and Hardware world, has one major drawback: organizing information (schematics, blueprints) and quality control are the boring parts that are not always pursued in a passion-driven and self assembled community. In the context of BME however, this latter aspect is critical for ensuring safety and efficacy of biomedical devices, and must go hand in hand with the adoption of open resources for medical applications.

We present here a **position paper** on the benefits and use of Open Source tools and platforms in BME specifically in Africa - a continent that needs to jump on the fastest, cheapest and greenest wagon to growth and self-sufficiency in healthcare or face being left behind. The adoption of these new methods of creating and thinking needs to be coupled with open standards and regulations for medical device safety. We thus argue that the new virtual sharing mentality should be wholeheartedly embraced, valorised and overseen by African universities through a common Open Source for Biomedical Engineering platform (OS4BME) rendering the development, and maintenance of medical equipment accessible to the African continent.

After a discussion on the potential of Crowdthinking (Section II) and BME in an African context (Section III), we describe the OS4BME project (Section IV) and its kick-start initiative in Nairobi in 2013 (Section V).

II. Crowdsourcing and Crowdthinking Platforms

Currently, there are several resource sharing platforms available on the internet. Their use is spreading throughout the developed World, starting from Europe and the US. The growing accessibility of these platforms, like any shared common resource, has resulted in the generation of huge amounts of garbage. Sifting the useless from the useful is a monumental task and requires experience in design and engineering as well as some skills in negotiating the now cluttered internet of things. More importantly, at present, there are no specific engines or platforms focused on the sharing of biomedical instrumentation and devices. This is because, by their very nature, biomedical devices possess stringent performance requirements to comply with regulatory standards to ensure patient safety.

In the past few years, various studies on social epistemology and group judgment aggregation have been published [16] [17] demonstrating both theoretically and practically the superior heuristic value of collective, non expert, knowledge compared to individual or small group assessment, based on consolidated rules and expectations. In 2006, Jeff Howe coined the Crowdsourcing Neologism in a futuristic article in Wired magazine [18]. Publishing of a neologism related to society cooperation in a magazine instead of in a traditional journal paper is a clear indication of how this new field is driven by a sort of creative talent of the community leading to tangible products for business and non-profit purposes [19].

Crowdthinking platforms are becoming important tools for design and development of new products. Platforms like Wikipedia [20], Thingiverse [21], YouMagine [22], Instructables [9] allow the generation of information that spans from text documents to complex designs and blueprints. Recently, the National Institute of Health of United States has proposed the 3D printing exchange portal [23], that collects 3D-printable files related to biomedical field from molecular and anatomical models to designs of prosthetic hands. Two more targeted initiatives are represented by Appropedia [24] and Open Source Ecology [25]. The first is focused on collaborative solutions in sustainability and poverty reduction, collecting projects on construction, energy saving, food, agriculture and also medical devices. The underlying theme is represented by the concept of Appropriate Technology, a term which indicates those technologies that are easily and economically used from readily available resources by local communities to fulfil their needs, compling with environmental, cultural, economic, and educational resource constraints of the local community [26]. The Open Source Ecology represents a network of people, farmers, engineers, architects and supporters, whose objective is to create an open technological platform that allows for the easy fabrication of the 50 different Industrial Machines that it takes to build a small civilization with modern comforts. Thus, several web based communities [27] have an active role in crowd-development and crowdthinking and also various FabLabs (Fabrication Laboratories) [28] are being born with the aim of bring technology to the people, empowering the creative process with the possibility of building real, physical objects. Using this approach healthcare issues such as prosthetics are also being addressed. For example, *Not Impossibles Project Daniel*, uses 3D printers to make prosthetic arms for children in worn-torn Southern Sudan [29].

Leaving aside large diagnostic and imaging equipment and prosthetic implants, the vast majority of biomedical devices have a large turnover and no one company monopolizes the market. They are also extremely diverse: examples are plasters, thermometers, hospital beds, sphygomanometers, etc. In this arena, there is huge scope for Crowd driven improvements and innovation.

In the context of BME, we still need a high level of supervision, to control the quality and to guarantee the respect of safety standards. By virtue of their access to the brains of the future, universities are the right (and perhaps the only) institutions to properly teach instruments for exploiting cloud and crowd based technology and "doing", while giving due importance to concepts, such as ethics, standards and regulations. However, the former is often unknown to even the most brilliant professors. More worrying is that fact that in very few universities do BME core competencies include knowledge on regulatory pathway development for medical devices. In addition, there are very few e-learning courses in BME and few universities make use of the newer technology platforms for teaching this discipline.

We define the Crowd, with a capital "C", as groups of individuals trained and assisted by institutions of technical and higher education, to design, innovate and build together through sharing. As such, the Crowd can and should consist of healthcare providers as well as engineers and technicians. If properly guided by standards and regulations, guaranteed by universities as the organ for control, certification, knowledge and learning, the Crowd is an enabling system for the design and development of medical devices. In addition, the Crowd philosophy can be extended to production processes so fostering local economic growth. In fact, the new methods of production now accessible to all do not require the delocalization of manufacture.

III. CONTEXTUALIZATION

A. Biomedical Engineering for Africa Today

As Nkuma-Udah et al. point out [3], there are few African universities which offer BME courses. Those that do are based on curricula which were designed for Western universities over 20 years ago and which place undue emphasis on niche subjects like MicroElectroMechanical Systems (MEMs), nano medicine and cell engineering and less on the learning of new, hard technology and equipment management, maintenance and repair [30]. Evidence from the *ASIALINK* project has demonstrated the value of developing expert skills through individualized programmes that cater to the specific social, cultural and technological needs of a region. While we are not advocating a complete revolution in BME teaching here, we are strongly in favour of the upgrading of curricula based on solid engineering principles (as outlined by Linsenmeier [31]) with new courses, new technology and new ways of thinking and problem solving, specifically adapted to the needs of countries with few resources. This approach is similar to that proposed by Tzavaras et al. [32] on computer enhanced education laboratories. Fusing the crowd design philosophy with the Biomedical Engineer's objective of improving human healthcare requires that patient safety and efficacy be the paramount concern and also the motivating force behind Crowd driven innovative biomedical device design. Biomedical devices must be designed with safety and efficacy in mind, and they should adhere to regulatory standards (albeit most of the countries in the region of interest have no regulatory authority for biomedical devices). Thus, the Crowd not only needs to be empowered with the technological know-how, but also be given the means to intelligently scan and filter the internet for useful open source materials without being overwhelmed by the choice available. To do so requires fundamental knowledge on biomedical devices, ergonomics, engineering and human physiology: this multidisciplinarity cries out for Crowd, but with a controlled accredited infrastructure capable of design-ranking and accreditation, as we discuss in Section V.

B. Social Context

Today, Africas healthcare systems are at a turning point. A growing urban middle class is willing to pay for better treatment. Donors and governments are now beginning to provide better healthcare facilities and increased access to medicine, at least in urban areas. There is no question that technology has played a key role in improving the quality and cost effectiveness of health services as well as access to health care facilities. Technology is at the heart of effective healthcare services helping medical and paramedical personnel in all stages of their work: from prevention to diagnosis, treatment and monitoring. Yet, technology entails huge investments in economic, physical and human resources; it comes with a price tag that can bear heavily on the limited resources of many African countries. To be able to function properly and safely, it requires an appropriate physical environment, proper care and maintenance, and skilled operators. However, Africa lacks the human resources needed to install, maintain, manage, upgrade, design and produce medical devices, leaving it ever more reliant on foreign technical expertise. Honourable initiatives, such as the Engineering World Health (EWH) [33] or the Amalthea Trust [34], which work in partnership with local hospitals, educational institutions and governments, providing training courses for improving local capacity, have a limited impact because they are not Africa-driven programmes. Thus, once the volunteer goes home, there is no-one left to take over.

We are fully aware that although professors, students and technicians maybe very enthusiastic with the idea of open source and Crowd driven biomedical device design, some Ministries of Health, or some powerful economic and other interest groups in developing countries could to be linked to major device manufacturers and therefore can block or hinder our initiative because their interests are threatened. For this reason, part of our project is also focused on creating awareness-raising activities and workshops targeting policy-makers, e.g., representatives of the Ministries of Health and

Education. Through the help of our funders we will develop advocacy campaigns for the recognition of the importance and relevance of biomedical and clinical engineering in the health care system. Policy makers will be made aware that local and locally trained Biomedical Engineers equipped with the means to create, design, innovate *and* fabricate are crucial for generating and managing a sustainable high technology health care system, which does not rely on foreign economic aid or volunteers. Indeed, our aim is to give the universities the tools, guide them through the platform and then let them research the best social conditions (at state level, society level, and so on) to turn the implementation of the project into a success. We are extremely sensitive about the issue of not imposing our ideas and cultural values on the People of Africa. Unfortunately, as recently observed by many African NGOs and local leaders, the passion for helping Africa is, more often than not, driven by the need to feel good about ourselves and seldom truly serves Africans or Africa to move forward. This push has to come from within Africa and should not be propelled by our need for self fulfilment or create publicity. The Daniel Project is a good example of this type of high profile, unsustainable aid.

IV. OS4BME PROJECT: THE CROWD PHILOSOPHY IN THE BME CONTEXT

What we advocate therefore is giving biomedical engineers in sub-Saharan Africa, through their universities, the tools and know-how they need to design, develop and maintain their own equipment based on the new open hardware and open source revolution, which is happening before our eyes. To achieve this ambitious goal, we outline three main objectives:

- the development of human resources in higher education in Biomedical Engineering in Africa,
- the creation of the expert-based OS4BME infrastructure, a sharing, making and repository platform (based on the customization and integration of already available web tools) for vetting, searching and ranking designs to propel continuous improvement and innovation;
- the making of a new genre of Biomedical Engineer (in Africa but also in the western countries) equipped with the capacity to exploit and develop innovative designs on the OS4BME platform and of discriminate use of web based and open source resources.

OS4BME capacity building efforts in design, entrepreneurship and regulation will ensure that Africa can timely exploit the open revolution. Setting up the OS4BME platform requires the creation of a professional BME working group, versed in the regulatory aspects of biomedical safety and standards, which is able to assess, vet and categorize projects, designs or blueprints and then make them available through the platform open repository. The philosophy is summarised in Figure 1.

Device development will be underpinned by quality and performance benchmarks to ensure safe human-device interaction, as the first step towards harmonisation of technology and biomedical device regulations across the African continent. At the same time, worldwide institutions involved in Biomedical Engineering, rapid prototyping, healthcare technology, higher education, medical device and prosthesis development can use the design, data and technology sharing platform as a reliable repository of innovative projects, ideas and networks for cooperative and excellent research and growth.

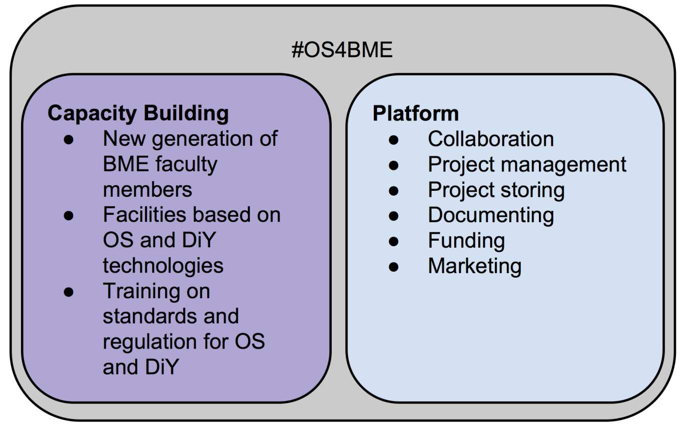

Figure 1. Scheme of the OS4BME project: integrating capacity building with a web platform for the creation of safe open source biomedical devices

A. Capacity building: A New Genre of BMEs Empowered with Crowd Thinking and Design Tools

The Open revolution is creating a deluge of information where only some “pearls” are contained. Building a new genre of BME professionals means making them able to find these cores of quality information. To do this, they have to be trained not with a new set of disciplines but rather with a new “forma-mentis” giving them the proper tool-set. Maths and Physics remain cornerstones but their use in design and prototypes dramatically changed in the last 10 years: nowadays, the designing phase can be interwoven with prototyping steps creating the new concept of pretotyping [35]. Having the possibility to do “tangible design” means optimizing the entire design process, but also enhancing new ideas and solutions.

The identification of the most suitable instruments and classroom management and organization is the first step to demonstrate the potential of open source in the BME context. We targeted three main areas of teaching, necessary to give a shape, a brain and to share the ideas:

1) Rapid prototyping: The term Rapid Prototyping (RP) indicates a group of technologies that allows the automatic fabrication of physical models based on design data using a computer. RP processes belong to the generative (or additive) production processes. In contrast to abrasive (or subtractive) processes, such as lathing, milling, drilling, grinding, eroding, and so forth in which the form is shaped by removing material, in rapid prototyping the component is formed by joining volume elements. In general, RP techniques follow a Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) approach. The object is designed using a computer (CAD), which then sends the instructions to the machine to obtain the desired shape (CAM), fabricated layer by layer. For the implementation of the RP principle several fundamentally different physical processes are suitable, such as photopolymerisation, conglutination of granules or powders by additional binders, extrusion of incipiently or completely melted solid materials [36] [37]. RP was originally conceived as a way to make one-off prototypes, but as the technology spreads more things are being printed as finished goods [38]. Although 3D printing is not competitive for mass production (millions of parts), it is perfect in fields where the customization of products is important: because the expense of making tools no longer figures in the equation, the economics of mass production will give way to mass customisation. Parts will then be made in production runs not of a million or even of a few thousand, but of one. Thus, 3D-printed products will continue to creep into the medical, dental and aerospace industries where clients are willing to pay a premium for custom products. In industries that are not built on "markets of one", 3D printing will help product designers accelerate the design process. 3D printers would also be invaluable in remote areas [39].

Thanks to the various Do-It-Yourself (DIY) communities, several models of Open 3D printers are now available on the Web. One of the most famous is the RepRap community [40] built around the ideas of Adrian Bowyer. He imagined a printer that can print its own parts, and hence through a process of self replication is able to spread this technology throughout the population [41]. The Fused Deposition Modelling (FDM) approach was chosen for its simplicity: a filament of plastic material is extruded through a hot nozzle following a predefined tool-path to build the various slices of a layered object [36]. All the parts of this 3D printer (there are several versions) are open source. The electronics is based on Arduino (see the next section), the software is open source and produces standard G-code files. Designs can be shared and any unprinted parts of the machine are easy to find in any DIY shop. Although, the quality of 3D printed parts made by a RepRap is not high, we believe it is the right starting point to teach the potential of 3D printing to newcomers. The design and printing process is completely transparent so that each step of the complex procedure is easy to follow and replicate. Furthermore, recently the open 3D printing has been indicated, for the African scenario, as an Appropriate Technology [26]. As a confirmation of this statement, the supply of printing filament material, even in remote areas, can based on plastic recycling, whose energy cost is lower than the price of commercial filament [42]. Open source devices which can produce useable filament from recycled post-consumer plastic are current available on the web [43].

2) Electronic Prototyping Systems: Until about ten years ago, electronic system design and development was a field accessible only to skilled users, such as engineers, technicians, physicists, etc. Each time an electronic control system was required in a project, the design process had to necessarily include the choice of microcontroller, of a communication system, of a power source, etc. This choice was then binding for the selection of further components, interfaces and programming software. In 2005, a team of designers led by Massimo Banzi created Arduino [44], a tiny board onto which a microcontroller was mounted together with all the necessary circuits and peripherals required for powering, communication and expansion. A revolution had begun: electronic control systems were not the bottleneck of prototyping anymore. With Arduino, even users without electronics and programming skills could integrate and electronic control system in their own project pushing the limits of complex system design and prototyping. The key factor of the Arduino platform is not only the board but also the easy-to-use programming environment, which allows unskilled users to program through a very intuitive C like programming language. These two factors allowed the birth of a huge user community, which empowered the home and even industrial and academic electronics world through the sharing of code, libraries and projects with open source license. The availability of a pre-made piece of code allowed people to focus their designs on the development of functional and challenging parts using other projects and codes as inputs for their own designs.

3) Content Management and Sharing platforms: As highlighted previously, the fast growing DIY community leaves several interesting projects to languish without documentation or with missing parts because a new, more interesting idea was released. Indeed, one of the most challenging aspects of cooperation in design and development is the organization and sharing of information and content. However, thanks to the revolution introduced by the blogging phenomenon, there are various free and open source Content Management Systems (CMS) available nowadays, which allow an easy and intuitive co-production of documents. These systems have been demonstrated to be useful even for the documentation of engineering and technical projects. MediaWiki [45] in particular is the core engine of the most famous web based encyclopedia Wikipedia. With MediaWiki or similar engines it is possible to create hypertexts made of a huge number of cross-linked pages allowing the creation of very detailed documentations and designs. MediaWiki is designed for the creation of text based documents with embedded pictures and table. Graphics and templates are very minimal allowing users to focus on the real content, which is a core feature of a concurrent design.

B. OS4BME platform design and implementation

The OS4BME platform is a virtual research infrastructure conceived as a facility for creating open excellence in Biomedical Engineering, comprising an array of design resources, including blueprints and performance data.

The platform will be composed of four sections, to fulfill specific tasks of the project lifecycle:

- a **needs identification** section, open to everyone (general public, healthcare providers), aimed at identifying problems using forums and surveys, and also at generating disruptive new ideas;
- a **project management** part, open to accredited Crowd and coordinated by the new BMEs, using specific project management tools (e.g., Redmine [46]);
- a **repository**, for free download of projects blueprints which passed the development phase and have been certified as compliant with standards;
- a **funding** section, for supporting selected OS4BME initiatives.

The development of a generic project is described in the following subsections; here it is important to highlight the differences with respect to the most popular web repositories [21] [22] [23]: the OS4BME platform will allow a coordinated development of a each single project and it will be downloadable only after vetting by a team of BME experts, which will assess and score designs; only those considered safe will be accessible for download. Moreover, full performance and safety documentation and instructions on calibration and maintenance have to be available. The OS4BME project goes beyond the mission of EWH or Amalthea Trust [33] [34], coupling capacity building to Africa-driven concurrent design, achieved through the OS4BME platform.

1) Platform management and maintenance: As already stated above, organizing information (schematics, blueprints) and quality control are usually the weak point of the self assembled communities for the "classic" open development. Furthermore, in the context of BME, devices demands in terms of safety and efficacy require a more structured design. For this reason, the OS4BME platform will foresee a Managing Group (MG), composed of the new genre of BMEs, with the aim at formalizing the problems and the needs that have to be solved and fulfilled, and series of Project Leaders (PLs) that will organize the specific project into horizontal or vertical tasks. While the MG have to be considered as a sort of "resident" group, any user can be the PL. The developers, above defined as Crowd, can participate to carry out the various tasks, according to their specific skills. From the formal point of view, there are no limits, in terms of academic title, to be part of the network as a user, as it happens with other developer communities; and it seems also reasonable that an academic group can be logged as a single unit with the same flag as a single user.

The maintenance of the OS4BME organization/platform (servers, people, meeting, summer schools and workshop organizations) will have of course a certain cost. We identified possible sources for the upkeep:

- fee payment from non-African Universities and Research Institutes. The participation in a program as OS4BME is to be considered prestigious, offering students the possibility to design useful biomedical devices, with a collaborative approach;
- financing from government. Considering the potential impacts on education on economy that the OS4BME project can develop, it seems reasonable that national and international governative organizations can fund this initiative;
- crowdfunding: specific projects, under the initiative of the project leader, can opt to access to Crowdfunding, publishing the campaign in the "funding section" of the OS4BME platform, or accessing other services such as Kickstarter [47];
- economic contribution from companies (see ensuing paragraphs): companies that want to commercialize the products developed thanks to the OS4BME platform can contribute as an investment to this "distributed" R&D sector;
- private donations.

2) Needs identification and project development: That the devices developed be useful in the African healthcare context is central to the OS4BME philosophy. Quite often biomedical equipment is left in the hands of healthcare workers through donations, whether they are needed or not. Local conditions such as availability of water, electricity and dust are quite different in rural hospitals, and these must also be taken into account. Thus, the most important criteria for identifying devices for the platform is that they respond to specific needs and provide specific solutions to daily problems that healthcare workers face. This requires close contacts with medical and nursing staff and local knowledge, thus the establish of formal relationships with hospitals is an important component in the implementation of the project. After the identification of the needs and the constraints, the project is formalized by the MG in terms of objectives, norms and standards. At this point, any user can propose himself as PL, organizing the work packages of the project, receiving feedback from other users who can participate in the various tasks according to their skills. At this stage of development, the decision on the validity of the project proposal is made in an indirect way by the Crowd itself, supporting or not a project. The PL has in any case the possibility to revoke a task and assign it different users if a deadline or a project specification is not respected. When a project is completed, the MG has the role to verify the quality of the specific products and its conformity to standards. A sustainable approach can be the assignment to three different Universities (not involved in the project) the task to built and test the product, according to the documentation provided by the developers. If this internal quality check is passed, the MG will ask three Hospitals, which are part of the OS4BME network, to test the product. After that, it will be available for downloading.

As depicted in Figure 2, the lifecycle of a project also comprises other two sections, the fund raising, and industrial upscale. While the latter is not strictly part of the OS4BME platform, a section of the platform is dedicated to support from the economic point of view. In particular, crowdfunding can be considered as a showcase for involving more partners; furthermore, the MG can help the PL to write a winning proposal to the various calls of funding agencies. Investor and business angels can also see a fertile ground to sponsor challenging ideas in OS4BME.

3) Project ranking: Starting from the consideration that more than one design can be proposed to fulfill a specific task/need, a classification is required in order to facilitate the users in the choice of the best solution for the specific case, on the basis of local conditions. Starting from the necessary requirement that the downloadable projects respect safety standards, we identified three different criteria for ranking:

Feasibility The feasibility criterion is related on the building phase of the device, and thus the following entries have to be taken into account: cost (raw material and time), components and material availability, construction simplicity (equipment, and thus skills needed), procedures for quality check.

Usability The usability of the specific design solution refers to those features related to the operating performance and operating condition of the device: accuracy, adaptability to various working conditions (e.g., salability of water, stable power supply), level of competences needed, easy of use, reusable/disposable.

Maintenance The maintenance criterion will provide a classification on the basis of the procedure needed to upkeep the device in optimal working condition: number and costs of maintenance interventions, necessity of specialized techni-

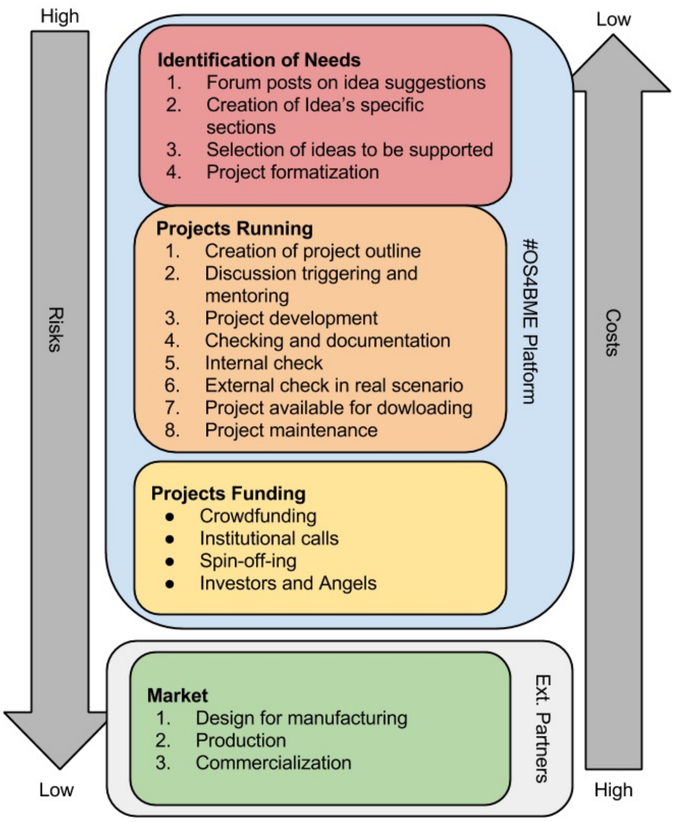

Figure 2. Project lifecycle, from the identification of needs to the design of a product, up to a possible commercial exploitation, under open license, by an external partner

cians.
After an initial score given by the developers and platform board members, the ranking will be updated on the basis of the users' feedback.

4) OS4BME as a flywheel for local economies: The authors are aware of the differences that exist between the design for prototyping and the design for manufacturing. The projects available for downloading are safe and compliant to standards, but are far from being defined as a "product" in the industrial sense (e.g., optimization of the production procedure, supply chain). Design for manufacturing, the business model, the business plan, the marketing campaign are beyond the limits of the OS4BME platform, which however encourages the entrepreneurial spirit. The biomedical devices are in general high added-value products, and authors believe that the platform can be a flywheel for local economies. In order to to guarantee a sustainable development of these "spin-offs", and ensure that the open-source aspect will remain intact, the following three requisites have to be satisfied:

- the products and their documentation have to continue to be open-source;
- the companies have to be located in Africa;
- the companies will economically sustain the OS4BME project.

Figure 3. Group photo from OS4BME class, hosted by the innovator Summer School, in the Kenyatta University Conference Center.

The MG will be in charge of signing agreements with these companies. It is also expected that some of the products will be copied by other entities in other countries (as it happens sometimes also with patented products), but they will be not branded as "OS4BME compliant".

V. OS4BME Class

To kick start the initiative and to demonstrate the potential of a regulated open source design and prototyping platform to academics and regulators/decision makers, we proposed a short term intensive course. The course was implemented in August 2013 in Nairobi, Kenya. Our aim was to introduce the OS4BME concept to the African Engineering community and thus create a small working group who will be involved in the set-up of the new platform. To fulfil this objective, the course was focused on the design of a biomedical device from first principles, its assembly and testing and discussion of regulatory issues in device development.

The OS4BME course was hosted by the Innovators Summer School held at the Kenyatta University Conference Center, Kenya and took place from the 12th – 16th of August 2013. The Innovators Summer School is an initiative of United Nations Economic Commission for Africa (UNECA [48]), and is aimed at fostering the economic development of Africa by powering the higher education of the African students. The key player in the initiative is the African Biomedical Engineering Consortium (ABEC [49]), a consortium of African universities with the common mission of bringing excellence to BME in Africa. Over 48 students, technicians and lecturers from the ABEC universities: Kenyatta University (Kenya), University of Nairobi (Kenya), University of Eldoret (Kenya), Addis Ababa University (Ethiopia), Makerere University (Uganda), Kyambogo University (Uganda), Mbarara University (Uganda), University of Malawi (Malawi), Muhimbili University of Health and Allied Sciences (Tanzania), University of Zambia (Zambia) and University of Pisa (Italy) attended the course (Figure 3).

After introductory lessons to explain the aim of the course, and some preliminary basics on RP Hardware, software, electronics, and safety regulations, hands-on sessions were provided, giving the students the opportunity to learn by doing. Following the spirit of the course, the free and open CAD/CAM software programs (FreeCAD [50], Slic3r [51], and Pronterface [52]) were adopted to introduce the design approach for 3D printing. For the electronics part, the Arduino platform was selected, for both price, ease of use and flexibility. All documentation was reported using Mediawiki. The keystone of the course was represented by the brainstorming coordinated by the authors with the help of Dr. Molyneux, a pediatrician from the University of Malawi, to understand the problems of a pediatric department in an African hospital context.

The discussion was centred on the respiratory problems of new born premature babies and the monitoring of breathing and body temperature. Together the class established the aim of designing and building a low cost device, for monitoring respiratory movements and temperature, able to shake the cot to resuscitate the normal breathing of the baby when it stops, and equipped with a sound and light alarm to call a nurse to the cot. The implementation of these features was defined together with students, after the brainstorming session. The discussion was focused not only on the functional aspects of the devices, but also on their cost, feasibility safety and reliability, giving the right direction to the project from its start.

After the definition of design specifications, students and attendees were divided into four thematic groups, on the basis of their previously indicated preferences: 1) mechanical design; 2) electronic design; 3) software design; 4) standard and regulation identification, and documentation. The subdivision in groups was fundamental in order to keep everyone involved in something they enjoyed: creativity is fed by passion and enthusiasm, boredom kills innovation.

The proposed approach led to the design and fabrication of an open source and low cost baby monitor (Figure 4) in the space of 3 days. The monitor was composed of three modules:

- an elastic band, to monitor the temperature and the respiration of the baby;
- a vibrating box, activated when the baby stops breathing for more than 15 seconds;
- a control unit, with a LCD display, 3 LEDs, sound alarms and all the control boards.

Students were encouraged to refer to ISO standards, such as IEC ISO 80601-2-56, with the aim of using these documents to help their work rather than a constraint.

At the end of the course an evaluation survey was conducted by the funders. Over 81% of participants expressed extreme satisfaction in the course, although a good proportion (46%) of them could have benefited from more time and previous knowledge on electronics, CAD and programming. In fact, only one participant had previously been exposed to open source technology. There was also interest in the regulatory aspects and standards in medical devices. As the participants were from different backgrounds, many had very little idea what medical devices are and the critical importance of safety issues in such devices. The action thus served to bring home the importance of this aspect during the design of instruments for BME.

VI. Conclusion and Future Work

The objective of the OSBME project was to develop and nurture resource sharing and technological self-competency through the establishment of a virtual platform containing ideas, blueprints, ranking criteria, FAQs and safety regulations for creating new, competitively priced and innovative biomedical devices. We envisage an OS4BME platform managed, regulated and monitored through an academic led pan-African organization, assigned with the task of collecting, classifying, vetting and disseminating information and know-how on the design and development of biomedical devices and instrumentation. In the long term, the sharing of ideas and designs should become the norm, allowing continuous user-driven improvements in healthcare.

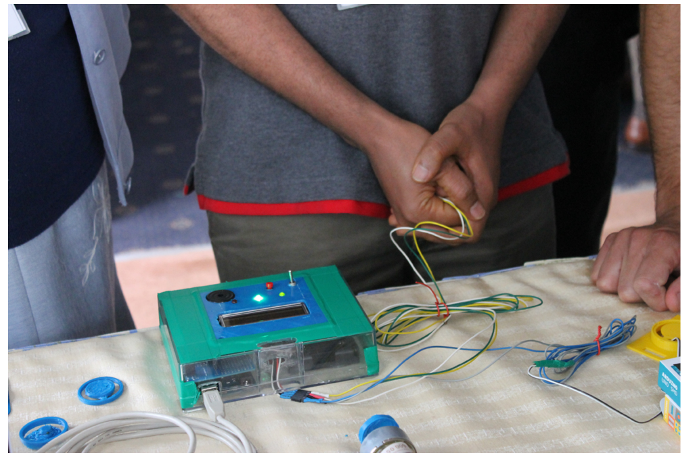

Figure 4. Some moments during the OS4BME class: preliminary test of the device.

A summer school was organized to kick off these ideas, with the aim to create a cohesive working group to initiate the construction of the the platform. The response from students, professors and technicians involved in the school was enthusiastic. It was crucial for participants to play an active role in the identification of the problem, selection of components, design, assembling and testing of the device and in the discussion of regulatory issues in the development of the device. Participants were able to gain a hands-on introduction to electronic system design and programming. All teaching materials, including course documentation, the baby monitor design blueprints are available online for the community to take on and develop further. The 3D printer and all components are now hosted at Kenyatta University's Faculty of Engineering (Figure 5) and being put to good use.

According to the funders' survey the course was an undoubted success. Most students and staff were unaware of the existence of tools, such as Arduino, FreeCad, Slic3r, Media Wiki, etc., let alone the power and implications of open source design and prototyping. The experience was instrumental in bringing this knowledge to the participants, and their keen interest throughout, particularly on 3D printing was apparent.

The blueprints of the devices developed in OS4BME, which comprise not only the designs, but also the proper guidelines and data for needs, quality and safety assessment will be shared by and through the OS4BME community. In the long term, the community will embrace not only African and European universities and research centers, but also hospitals, giving the possibility, through Creative Commons-like licenses, to fabricate medical devices that will greatly enhance the qual-

Figure 5. Final ceremony of the OS4BME summer school. The 3D printer, printing materials, Arduino electronic boards and the baby monitor were donated to Kenyatta University.

ity of healthcare in developing countries. As a consequence, the project will also foster economic growth both by creating a substrate of highly-skilled personnel and by transforming ideas generated by OS4BME open and crowd approach into commercial products. In addition, national legislation on medical devices amongst the ABEC countries is highly fragmented and/or non-existent. The infrastructure will provide a common substrate through which local biomedical device regulations can be harmonised with the specific contribution of local regulatory authorities.

Although there are several resource sharing platforms available as well as several courses on RP, digital design and embedded electronics, none of these is dedicated to biomedical devices. This is because biomedical devices must be designed first and foremost with patient safety and efficacy in mind. The OS4BME infrastructure, managed by the new genre of biomedical engineers, can be the tool to address this challenge, and its implementation is our objective in the next few years. The initial cornerstone of this project was an intensive course, the first of its kind, addressing safety, ergonomics, biomedical device design, and RP in an integrated manner. Further courses of a similar nature are planned at all participating universities. This open education and crowd-based design model could be exported to universities in developed countries. Let us not forget that the true beneficiaries are the students, who are exposed to the web world at an early age. Educators should keep pace with the open revolution and their pupils' modes of learning, adopting and integrating the approaches proposed here in the teaching curricula. When embraced, the presented Open Source tools and sharing mentality will give BME a new impetus, open to novel teaching, learning, and design paradigms.

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