Safety by open design

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Background

• UNECA recognises the **importance of Biomedical Engineering** for improving healthcare in Africa (2011)

• University of Pisa invited to attend the first summer school at Kyambogo University (2012)

• **Creation of ABEC** (2012) and focus on Africa-relevant BME
# Background

<table>
<thead>
<tr>
<th>Period</th>
<th>Place</th>
<th>Hosting Institution</th>
<th>Topic</th>
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<td>1&lt;sup&gt;st&lt;/sup&gt; ISS</td>
<td>2012</td>
<td>Kampala (Uganda)</td>
<td>Universities formed the Africa Biomedical Engineering Consortium (ABEC)</td>
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<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; ISS</td>
<td>2013</td>
<td>Nairobi (Kenya)</td>
<td>Introduction to Biomedical Device Regulations and Rapid Prototyping</td>
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<td>3&lt;sup&gt;rd&lt;/sup&gt; ISS</td>
<td>2014</td>
<td>Dar Es Salam (Tanzania)</td>
<td>From Making to Marketing</td>
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<td>4&lt;sup&gt;th&lt;/sup&gt; ISS</td>
<td>2016</td>
<td>Addis Ababa (Ethiopia)</td>
<td>Application of mobile phones in healthcare product design and development</td>
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<tr>
<td>5&lt;sup&gt;th&lt;/sup&gt; ISS</td>
<td>2017</td>
<td>Cairo (Egypt)</td>
<td>Biomedical and Clinical Data and Informatics for Development in Africa</td>
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Life cycle of a medical device

- Defined on the basis of the intended use
- Classification and Certification (I, IIa, IIb, III)
- Risk management: ensuring safety of patients, users, bystanders, healthcare providers, environment
- High cost!

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Life cycle of a medical device

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Use open source approach and appropriate technologies for reducing development cost!

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Safety and innovation by open and collaborative design

What: Developing a medical device by sharing ideas and concepts, design files, documentation, source-codes, blueprints and prototypes, testing results and all collected data

Why: accessibility, sustainability, lower costs, improved performance and safety because everyone can review the design dossier
HOW

- Open access **e-infrastructure**
  - Innovators and designers create a profile
- **Open source design**
  - No IP protection, Open Data on device performance, blueprints
- **Compliant** with EC Medical Device Regulation
- **Peer-to-peer** review
  - e-infrastructure allows open access to all designs under development
- Expert, open **mentoring** from Academia and Industry
- **Needs based Design**
Quality means safety

- Quality and safety guidelines for biomedical devices, under the guidance of international standards and European MDD (soon MDR), are the foundations
  - Technical state-of-the-art in safety
- Expert mentoring will ensure that the designs comply to highest technical standards at all steps
  - Mentors from Academia and Industry
Open means:

• Sharing of open data on device statistics (performance, field tests, quality control)

• Sharing of mentor comments and design errors or dead ends

• Needs based design on the highest priority medical devices backed with research on current disease burdens
Open source co-design of new solutions to face the current and future global healthcare challenges

BY

Exploiting networking, knowledge sharing and safety on rapid prototyping of new ideas and criteria and performance data

THROUGH

A open e-Infrastructure, UBORA

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UBORA: Our objectives

- Promote education
- Stimulate innovation
- Harmonisation and Safe Design via UBORA
UBORA in the life cycle of a medical device

Use open source approach and appropriate technologies for reducing development costs and increasing safety!
UBORA: Euro-African Open Biomedical Engineering e-platform for Innovation through Education

The EU funded project aims at creating an e-platform – 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.

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Last name

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Secret password again
Secret password again

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UBORA e-infrastructure: Risk Classification

- Classification according to the Medical Device Regulation MDR 2017/745
  - From I (Low Risk) to III (High Risk)
  - Decision tree with 30 questions (mainly binary, e.g. Yes/No)
  - Validated with the help of expert consultant
UBORA e-infrastructure: Standard identification

- Identification of **Horizontal Standards** applicable to a Medical Device
  - Focused on the «ontology» of the device
  - Hard to identify using keywords in a search engine
  - Decision tree with 30 questions (mainly binary, e.g. Yes/No)
  - ISO and IEC standards
  - Validated with the help of expert consultants
Projects collaborated on UBORA e-platform

UBORA features a project collaboration tool to guide the process of developing a biomedical device in an open-source manner that is in accordance with the international safety standards. All projects are overlooked by the UBORA certified mentors. You can freely create a new project or join existing ones to start collaborating with the community.

Breast Pump

Economic and Ecological Breast Pump with Cooling and Preservation System of the Breastmilk. The project consists in a manual breast pump with an air-water cooling system.

Clinical need: Prevention of pathology or disease
Area: Pediatrics
Device classification: Ila
Economic and Ecological Breast Pump with Cooling and Preservation System of the Breastmilk

Project description

The leading causes of deaths in children under 5 are: pneumonia, diarrhoea, sepsis and severe malnutrition. Breastmilk is more than just food for babies – it is also a potent medicine for diseases prevention that is tailored to the needs of each child. Breastfed babies are less susceptible to ear infections, diarrhoea, pneumonia and other childhood illnesses.

Our project fights not necessary and wrong use of artificial milk, caused by mother’s illiteracy or poverty and use of unsafe water. It supports women who choose to breastfeed assisting breastmilk production and preservation without electric energy.

Addressed target population is developing country population.

The project consists in a manual breast pump with an air-water cooling system. Through the water evaporation the collected breastmilk is cooled and preserved at 15°C for 24 h, 5 times more than the storage time at room temperature.

Our technology is very easy and cheap to be accessible to illiterate and poor people as well. The cooling system is made with the smallest possible number of pieces and it is very easy to assemble and clean. The instruction book will present only images, without words.

The system works and is made only with available, economic and recyclable materials to be completely sustainable.
Have a need for a Bioengineering Solution?
Find a suitable Bioengineering solution to healthcare problems through open discussion.

Looking for something else?
Find material and resources for design selected by UBORA mentors.

Support UBORA
You can support UBORA by spreading the word, by collaborating on open-source projects or by supporting financially.

Donate

An alpha version is being used by 17 universities across Europe and Africa. The final release open to any registered user will be in September 2018.
Conference: 1-2 September 2018

First International Conference

COLLABORATIVE BIOMEDICAL ENGINEERING FOR OPEN SOURCE MEDICAL TECHNOLOGIES

September 1-2, 2018
Convention Center "Le Benedettine" - Pisa (Italy)

CALL DEADLINE:
June 30, 2018
Safe innovation: On medical device legislation in Europe and Africa

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\end{itemize}

\begin{abstract}
\textbf{Keywords}: Medical devices regulation; Standards; Africa; Europe; Open Source Medical Devices

\textbf{Abstract}: The principal motivation for regulating medical devices is to protect patients and users. Complying with regulations may result in an increase in development, manufacturing and service costs for medical companies and ultimately for healthcare providers and patients, limiting the access to adequate medical equipment. On the other hand, poor regulatory control has resulted in the use of substandard devices. This study aims at comparing the certification route that manufactures have to respect for marketing a medical device in some African Countries and in European Union.

\textbf{Methods}: We examined and compared the current and future regulations on medical devices in the European Union and in some countries in Africa. Contextually we proposed future approaches to open design strategies supported by emerging technologies as a means to enhance economically sustainable healthcare system driven by innovation.

\textbf{Results}: African medical device regulations have an affinity to European directives, despite the fact that the latter are particularly strict. Several states have also implemented or harmonized directives to medical device regulation, or have expressed interest in establishing them in their legislation. Open Source Medical Devices hold a great promise to reduce costs but do need a high level of supervision to control their quality and to guarantee their respect for safety standards.

\textbf{Conclusion}: Harmonization across the two continents could be leveraged to optimize the costs
Thank You!

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

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