

Deliverables from International Cooperation on an NIH-Funded Biomedical Engineering Project in Africa

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Currently the Head of the Department of Civil Engineering at the University of Ibadan, Professor Coker is also the Executive Director of the Nigeria Network for Awareness and Action for Environmental Health – an NGO devoted to Environmental Sustainability. The academic goal of Professor Coker is to provide exemplary leadership and mentoring to colleagues and to make a real difference in the Environmental Health Sector. Hence his research has focussed on biomedical engineering, health and safety, public health, water resources management, waste audit, waste recycling, waste management, environmental impact assessment and remediation studies. He has participated in many local projects such as Fadama Development Project, Water Sanitation and Hygiene Project(WASH) as well as internationally-funded projects such as those of UNICEF, UNDP, UK Aid, US National Institutes of Health, WHO, World Bank etc.

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DELIVERABLES FROM INTERNATIONAL COOPERATION ON AN NIH-FUNDED BIOMEDICAL ENGINEERING PROJECT IN AFRICA

Through the Frameworks grant provided by the National Institutes of Health (NIH) Fogarty International Center, an interdisciplinary team comprising faculty members from the medical, business and engineering schools at Northwestern University (Chicago, IL) in collaboration with faculty members from the University of Ibadan, Nigeria, University of Lagos, Nigeria and University of Cape Town, South Africa have been able to record quantifiable progress in achieving the specific goals of a 5-year grant received in September 2013 for developing innovative biomedical engineering (BME) programs in Africa.

Several key deliverables comprise the designing of biomedical products. For example, to improve pediatric surgical outcomes, and based upon the needs analysis performed by a local pediatric surgeon in Nigeria, an Infant Warming Device for regulating temperature during pediatric surgeries has been designed, prototyped, and tested under laboratory conditions - it is currently being prepared for clinical testing. The warmer came about as a result of identifying problems and challenges being experienced in Nigerian Hospitals by Nigerian doctors and has been developed by an international team of faculty and students from all four universities. In addition to the infant warmer, engineering, medical, and business faculty in Nigeria have worked with colleagues from the US and S. Africa to develop technologies and products for monitoring wound exudate from burn victims, crushing and storing medical needles and sharps, and housing laboratory animals for metabolic studies. These case studies, specifically the international collaborative design process used to move these solutions forward, are described in the paper.

Moreover, investigators comprising African engineers, scientists, and medical doctors are working to develop a book on Biomedical Engineering for Africa. This book will address what it means to practice the BME discipline within an African context. In addition, an African-based research journal – *Global Health Innovation* – has been launched by the University of Cape Town through support from the Frameworks grant. The journal has the mission of advancing and disseminating knowledge on all aspects of social and technological innovation for improved health and healthcare, with an emphasis on research addressing developing settings such as those found in Africa. These deliverables, along with the process for creating them, are also described and discussed herein.

Introduction

Previous studies have shown that limited infrastructure and human resources have significantly reduced the quality of medical care available in low and middle income countries as compared to developed nations [1]. While efforts have been made to apply Western healthcare systems and technologies to these resource-limited settings, results have been mixed at best [2]. One path to improving healthcare in these challenging environments is to engage with local clinicians and partner them with engineers and entrepreneurs to create “locally grown” medical devices and methods. As mentioned in a previous paper summarizing the specific aims of the grant funding this work, “... local research-focused universities can (and should) play a critical role in this scenario.” [3]

For the past five years four universities from three different countries and two continents have taken steps to improve the biomedical infrastructure in sub-Saharan Africa - starting with Nigeria. Through a series of four specific training opportunities (described briefly below and in-depth elsewhere [3]) engineering, medical, and business faculty from these

universities gain experience identifying unmet medical needs in low-income settings, and in turn, devising solutions to meet these needs with the intent of commercialization. This paper outlines the process of, and the progress made in, developing solutions to three medical problems identified through this international collaboration. In addition, it describes two other deliverables of significance (an international open-access journal, *Global Health Innovation*; a book on BME written for Africa by Africans) that have grown organically out of these training opportunities.

Training opportunity - Northwestern University (NU), USA

For each of the past five years, the BME department at NU has hosted 2-4 engineering and/or clinical faculty from the University of Ibadan (UI) and the University of Lagos (UNILAG) for a month-long experience in which they gain professional experience by: 1) participating in and presenting at the annual meeting of the Biomedical Engineering Society (BMES); 2) observing and participating in relevant BME courses including the senior BME capstone design course sequence; 3) tours of BME departments, and meetings with associated faculty, within the greater Chicago-area; 4) meetings and professional interactions with faculty from various schools within NU; 5) visiting and conducting research in NU's research and development laboratories and facilities.

Training opportunity – Kellogg Field Studies, Africa

The Kellogg Field Studies provide faculty from UI and UNILAG a multi-week opportunity to explore the healthcare pyramid for a specific developing nation within Africa (e.g., Tanzania, 2014). This experience introduces participants to all levels of the pyramid including healthcare providers in rural settings to the Minister of Health in that nation. Participants learn to identify the unmet medical needs as well as the challenges associated with introducing new medical technologies in that nation.

Training opportunity – University of Cape Town (UCT), South Africa

For the past five years faculty from UI and UNILAG have participated in a quarter-long experience through the Division of Biomedical Engineering at the University of Cape Town. While in this program faculty participate in a set of courses including *and Medical Device Design* [4]. In these courses students (and, in this case, visiting faculty) learn and apply the design process to develop a solution to unmet needs found in a local community in Cape Town and/or brought from Nigeria, respectively. The needle disposal device described below was designed and developed by a group of visiting faculty from UI participating in this training program during the winter of 2017.

Training opportunity – UI and UNILAG, Nigeria

From 2013-2017 faculty from all four of the collaborating universities on this grant have met in Nigeria (alternating yearly between Lagos and Ibadan) for a week-long conference/workshop to plan the goals for the year, present on the past year's work, and to plan deliverables of significance for the grant. During the F'16 event hosted by UI, the participants determined that the following would serve as key deliverables: 1) launching of new an open-access journal in the biomedical engineering and global healthcare space; 2) publishing a book on BME written by Africans for African students and faculty; 3) 2-3

medical devices that had been developed through collaborations facilitated by this grant. These deliverables are described in detail below.

Description of Major Grant Deliverables – Global Health Innovation Journal

While there are many published biomedical engineering and innovation focused journals (NU archives 85 and 132, respectively), there are fewer journals with a focus on global health (NU archives 19), and there is not a single one at NU that addresses all three areas. While work that can be categorized as biomedical engineering within the context of global health would be suitable for publication in many BME journals, it should also be shared with public and global health audiences. In addition, innovation requires more than technological advances, it requires a consideration of socioeconomic and cultural factors, especially in developing settings and the global health context. A biomedical engineering journal would not necessarily be seen as one that reports on these non-technical factors that impact technology implementation and are often barriers in the African context.

Scientists, engineers, clinicians, and entrepreneurs focused on improving healthcare in developing countries may have difficulty in gaining access to subscription journals. This limits their ability to share their research and to engage with published research that is relevant to their context of work.

There are not many journals that provide a freely available platform for scientists in developing countries to publish research involving innovative biomedical and healthcare practices. A simple search of the *Web of Science* database using “Publication Name: (Global Health)” returned 631 records, >89% of which were published by the open access journal *Globalization and Health*.

Globalization and Health, part of BMC Publishing, has been publishing open-access articles since 2005. Its mission is to provide a journal for studies that address “... public health and well-being within the dynamic forces of global development.” The editorial (12 members) and advisory (44 members) boards for the journal represent 6 continents and 17 countries; as a result, the international impact of this publication is significant. The focus of the studies published in this journal however is not on engineering and development of technological solutions, nor specifically on innovation in its broader conceptualization, but rather on practices and policies that directly influence health care. While there is overlap between the mission of this journal and that of our own, there is a clear distinction as well.

Global Health Innovation is a peer-reviewed open access journal that is published twice a year by the University of Cape Town Libraries. The mission of the journal is shared below:

The journal has the mission of advancing and disseminating knowledge on all aspects of social and technological innovation for improved health and healthcare, with an emphasis on research addressing developing settings and with a developmental focus.

Studies across a broad range of innovation activities are covered. Areas of interest include, but are not limited to: design, implementation and evaluation of innovations in the global health context; development and implementation of appropriate health technologies; theories and methodologies that support health innovation practice; training and curricula in global health innovation; and interdisciplinary research that highlights the

interface between technology, health sciences and social sciences in achieving impactful health innovation.

The editorial board for *Global Health Innovation* comprises the PIs on the Frameworks grant, as well as members engaged in biomedical engineering with a global health perspective from six countries, and four continents, with developing countries being well-represented.

Table 1. Editorial board members – Global Health Innovation

Name	Role	Discipline	University	Country
Douglas, Tania	Editor-in-Chief	BME and Innovation	University of Cape Town	South Africa
Barros, Allan Kardec	Member	BME, EE and Eng Physics	Universidade Federal do Maranhão	Brazil
Coker, Akinwale	Member	Civil Eng and Technology	University of Ibadan	Nigeria
Fourie, Pieter	Member	Global Health	Stellenbosch University	South Africa
Gatchell, David	Member	BME and Product Design	Northwestern University	USA
Glucksberg, Matthew	Member	BME and Global Health Innovation	Northwestern University	USA
Lahiri, Uttama	Member	Electrical Eng	IIT Gandhinagar	India
Leautaud, Veronica	Member	Biological Sciences, Bioeng, Education	Rice University	USA
Mkandawire, Theresa	Member	Civil and Env Eng	University of Malawi	Malawi
Murphy, Robert	Member	Global Health and Infectious Diseases	Northwestern University	USA
Osuntoki, Akinniyi	Member	Biochemistry, Molecular Biology	University of Lagos	Nigeria
Palamountai, Kara	Member	Business Management and Global Health Innovation	Northwestern University	USA

Description of Major Grant Deliverables – Book on BME for Africa

One of the major obstacles to improving the biomedical infrastructure in sub-Saharan Africa is a lack of established degree-granting programs in biomedical engineering. While there are examples of long-standing programs (e.g., the Biomedical Engineering program at the University of Cape Town), most universities have only developed their programs within the past 10 years, if at all. It is not an exaggeration to state that biomedical engineering as a discipline is new to the majority of the African continent [5, 6].

Given the developing state of biomedical engineering education in Africa, it is not surprising that there are limited publications that may act as pedagogical guides for faculty developing programs and courses in this area. One of the major deliverables stemming from this five year collaboration is a book on BME written by Africans for Africa. Below we share the process for designing and developing the book followed by a brief synopsis of its current status.

Current Status of Book

There are currently six chapters of the textbook that are nearing a state where they are ready for completion. Each chapter is outlined below.

- Chapter title: *Creating a Department of Biomedical Engineering and an Undergraduate Program - the University of Lagos Experience*

This chapter describes and discusses the following topics:

- The history of the university including when it established undergraduate (2017) and postgraduate (2010) programs in biomedical engineering.
- The location of the program, i.e., whether the BME degree granting programs at UNILAG should be housed in the medical school (BIOMEDICAL engineering) or the engineering school (biomedical ENGINEERING). Topics for discussion include: 1) on which campus should the department reside (medical or engineering); 2) who is responsible for administering the degrees, including providing proper academic and research facilities as well as shouldering primary teaching responsibilities.
- Naming of the department, e.g., “Biomedical Sciences and Engineering” versus “Biomedical Engineering.” Much of this naming discussion is connected to aforementioned topic of which school and campus should house the department.
- Motivation for developing an undergraduate degree in BME.
- Overview of the undergraduate curriculum including coursework, laboratories, and teaching staff.
- Implications for research including a movement toward multi-disciplinary collaborations within and across schools.
- The vision of the BME department:
 - Improve and extend the technological capabilities of medical personnel in healthcare delivery;
 - Operate a department which serves as solution hub for research, medical device manufacturers and clinicians;
 - Train highly skilled biomedical engineers capable of meeting local needs and global challenges in the biomedical technology space; and

- Become the foremost center of excellence for BME in Africa.

- Chapter title: *Biomedical Engineering in Ethiopia*

This chapter describes and discusses the following topics:

- A history of biomedical training in Ethiopia including motivating factors for developing BME degree granting program at the undergraduate and graduate levels at four distinct universities.
- Drivers of biomedical engineering in Ethiopia including the role of the: 1) Ministry of Education; 2) Ministry of Science and Technology; 3) Ministry of Health; 4) the Ethiopia Society of Biomedical Engineers and Technologists.
- A description of Ethiopia's 2010 Growth and Transportation Plan (GTP) and its impact on BME education.
 - Goal is to reach 50% import substitution of pharmaceutical and medical devices by 2020.
 - This, in turn, should incentivize manufacturers to establish an industry for producing and assembling medical devices.
 - Such an industry would need to be supported by biomedical engineers – one of the primary factors driving the expansion of BME education in Ethiopia.
- Description of BME programs at four national universities: Addis Ababa University - AAU (ugrad, post-grad); Jimma University (ugrad, post-grad); Hawassa University (ugrad); Gandor University (ugrad).
 - It is interesting to note that AAU will be launching a BME PhD program in partnership with universities in Finland and South Africa.
- Challenges for the BME field in Ethiopia
 - Regulations: medical devices are categorized as a type of pharmaceutical in Ethiopia which require a medical license to operate. BMEs are not currently equipped with these licenses and therefore are not allowed to operate, service or sell these types of devices.
 - National awareness of biomedical engineering
 - Salary and benefits for biomedical engineers
 - Career trajectory of BMEs
 - Training required to be a BME
- Conclusion
 - The need for BMEs in Ethiopia outstrips the supply. This lack of supply should create a “market pull” dynamic where BME graduates are in high demand. Unfortunately BME is not a well-recognized and understood profession. A recent publication by the World Health Organization (WHO) is a significant step toward addressing this issue.

- Chapter title: *A Needle Disposal Device for Use in Low-Resource Settings*

In addition to the information provided below, this chapter provides the following:

- A detailed decomposition of the designed artifact and how each sub-system/component satisfies its requisite function, e.g, the use of magnets to separate metallic components of sharps from their plastic housings.
- A cost analysis for manufacturing and assembling the device locally in South Africa.

- Chapter title: *Medical Device Concept for Burn Wound Exudate Detection*

In addition to the information provided below, this chapter provides a detailed discussion of:

- The impact of burn wound infection.
- The significance of wound exudate strikethrough.
- The current practice of wound care in the burn unit of the University College Hospital in Ibadan.
- The current design including:
 - A clear communication of the users' needs, design requirements, and relevant design specifications (including metrics and target values).
 - A system-level diagram which clearly communication the modular architecture of the solution.
 - A description of the testing results, including benchmarking of data transmission alternatives integral to the proper function of the design.

- Chapter title: *The Regulation of Medical Devices in Africa*

This chapter describes and discusses the following topics:

- A review of literature linked to medical device regulation in selected African countries including: Algeria, Angola, Egypt, Ethiopia, Kenya, Nigeria, South Africa, Sudan, and Tanzania
- Implications of these regulations for the development of the medical device industry in Africa.

- Chapter title: *User-Centered Design in a Health Innovation Course to Address Hearing Loss in the Elderly*

This chapter describes and discusses the following topics:

- A graduate course titled, "Health Innovation and Design", which addresses the challenge of delivering quality healthcare in a resource-limited setting. Through the use of innovation one may, in theory, drive down the cost of medical devices and solutions.
- The design process used in the course including an overview of design thinking as well as an introduction to the Phillips Co-Create Four-Phase Model: 1) Discover; 2) Frame; 3) Ideate; 4) Build.
- Assessment of student learning in the course.
- Reflections on students' experiences taking the course.

Description of Major Grant Deliverables – Medical Devices

Medical Device #1 - Infant Warmer

What's the problem?

Surgical outcomes, especially those involving prematurely born infants (neonates), are directly linked to the temperature of patient's body pre-, intra-, and post-operatively [7]. Significant drops in body temperature (1.6 °C within the first hour) have been shown to rapidly occur after induction of anesthesia which can lead to increased perioperative morbidity and mortality. The effects of the anesthesia, compounded by opioids give for pain relief, often delay the return to normothermia (i.e., the return of the body's temperature to normal limits) for up to 2-5 hours post-operation.

Who's it a problem for? What efforts have come before? How have they failed? Where have they succeeded?

In resource-challenged settings the temperature of the neonate's surroundings during surgery is often maintained through off-the-shelf solutions such as hot water bottles and consumer-grade electric blankets. Limitations of these solutions include limited control of heating as well as no built-in temperature readings. As a result, patients are either warmed too much or not enough leading to occasional morbidities. While there are effective solutions on the market (e.g., forced air warming blankets), these are cost-prohibitive for NICUs in developing nations.

How are our efforts different? What is the current status? What are the next steps?

Our goal has been to design a safe and affordable device for maintaining normothermia during abdominal surgeries of pediatric patients the University College Hospital at the University of Lagos, Nigeria. The device is intended to be used for patients up to three years of age with body masses up to 3.5 kg.

Medical Device #2 - Needle Disposal Device

What's the problem?

The management of medical waste, specifically "sharps" (e.g., needles, syringes, lancets) is an ongoing challenge for developed countries and even more so for the developing world. Efforts to capture these products in sharps containers only address part of the problem: reducing accidental sticks in the healthcare environment [8, 9]. They do not, on their own, address the end-of-life concern of what is done with the containers themselves. In developed nations these containers are often incinerated, a process that is not often available in lower resource settings. As a result, one could argue that sharps containers used in resource-limited environments simply delay the accidental sticks that they are meant to prevent. The challenge here is to create a point of use device for destroying and storing the sharps directly after use.

Who's it a problem for?

While developed nations continue to update their approaches to the management of medical waste, medical workers in developing countries are often not familiar with the procedures required for proper waste management. As a result "... the management of wastes is often relegated to poorly educated laborers who perform most activities without proper guidance and insufficient protection." [9] Therefore there is a need for a point of use device (as mentioned above) that is not only effective but also easy to use and requires little to no additional training of the user.

What efforts have come before? How have they failed? Where have they succeeded?

Past efforts to handle unwanted needle sticks in developing countries have focused on the use of sharps containers (WHO references). While these containers have been shown to reduce the numbers of needle stick injuries in health care settings, they do not address exposure throughout the entire cradle-to-grave consumption chain. In developing nations containers may end up at dumping sites which are frequently visited by individuals scavenging for goods. In their current intact state the needles are still dangerous even if they have been temporarily housed in a separate container.

How are our efforts different? What is the current status? What are the next steps?

The goal has been to develop a safe, simple, on-the-counter needle disposal device that would effectively leave sharps unusable (e.g., by bending, breaking, cutting or crushing it) and allow for the detritus to be effectively disposed of with other forms of medical waste [10].

Medical Device #3 - Wound Exudate Detection

What's the problem?

According to the World Health Organization (WHO), burns are the fourth most common type of medical trauma identified by public health officials. Approximately 90% of these burn events occur in low- and middle-income countries resulting in over million being affected and 238,000 deaths per year. The large majority of these deaths are caused by infections, incurred by patients because of the lack of a protective skin barrier created by the burn as well as an impaired immune response. The rate at which infections occur is compounded by the fact that burns are heavily exudative, in turn, creating a nutrient-rich medium ideal for colonization and proliferation of microorganisms. The goal of the healthcare provider is to clean the patient's wound dressing before the exudate leads to an infection.

Who's it a problem for?

Medical staff, especially nurses and doctors working in burn units in developing nations, have the daunting task of monitoring the wounds of its patients. In one such unit at University College Hospital in Ibadan, a 12-bed ward can see up to 87 acutely burned patients per year. In this setting it is not unusual for cross-infection to occur between patients because of their close proximity.

What efforts have come before? How have they failed? Where have they succeeded?

In developing nations burns are treated with a 4-layer dressing: 1) the first layer, placed directly on the wound of the patient, is antiseptic impregnated paraffin gauze that serves as a non-adherent layer; 2) the second layer comprises a thin layer of gauze that acts as a wick, transmitting the wound exudate to the 3) third absorbent layer of cotton wool (Gamgee); 4) the first three layers are wrapped in a crepe bandage which is used to keep the dressing in place. The signal for a dressing change is the presence of strikethrough, an indication that the exudate has soaked through the first three layers of the dressing. When strikethrough occurs the patient is at significant risk for infection unless the dressing can be changed almost immediately.

How are our efforts different? What is the current status? What are the next steps? Medical professionals in developing nations need a reliable method of being alerted when strikethrough is imminent. This method must result in a minimal interruption of workflow, work in erratic power environments, be sanitisable if it comes into contact with patients, and affordable for low-resource medical centers.

Conclusions:

For the past five years engineering, medical, and business faculty from four universities in three different countries and spanning two different continents have come together to address the biomedical infrastructure in sub-Saharan Africa. Through these collaborations two BME degree granting programs have been created in Nigeria as well as the deliverables of significance described above. Most importantly, however, is the community of practice that has been achieved among these universities. Working relationships have been created that will continue beyond the limits of this grant. As case and point, Professor Sridhar at the University of Ibadan has begun collaborating with the *Engineering World Health* team at Northwestern University in the United States. Professor Gatchell will continue to travel to Nigeria independent of the grant to help bring the infant warmer to market. The book and journal described above also serve as collaborative efforts which will keep this community together and thriving.

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