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An Example-Centric Tool for Context-Driven Design of Biomedical Devices

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ABSTRACT

Engineering is one of the most global professions, with design teams developing technologies for an increasingly interconnected and borderless world. In order for engineering students to be proficient in creating viable solutions to the challenges faced by diverse populations, they must receive an experiential education in rigorous engineering design processes as well as identify the needs of customers living in communities radically different from their own. Acquainting students with the unique context and constraints of developing countries is difficult because of the breadth of pertinent considerations and the time constraints of academic semesters. This article describes a tool called Global Biomedical Device Design, or GloBDD, that facilitates simultaneous instruction in design methodology and global context considerations. GloBDD espouses an example-centric approach to educate students in the user-centered and context-driven design of biomedical devices. The tool employs real-world case studies to help students understand the importance of identifying external considerations early in the design process: issues like anthropometric, contextual, social, economic, and manufacturing considerations amongst many others. This article presents the rationale for the tool, its content and organization, and evaluation results from integration into a junior-level biomedical device design class. Results indicate that the tool engages students in design space exploration, leads them to making sound design decisions, and teaches them how to defend these decisions with a well-informed rationale.

Key Words: design, humanitarian, biomedical devices

INTRODUCTION

Engineers must learn how to solve problems in an efficient and effective manner, work with peers across countries and cultures, and communicate ideas to diverse audiences [1]. However, educating engineering students about the societal and global context often conflicts with strict technical coursework requirements. One solution to this is framing engineering projects in real-world contexts, so that students learn technical coursework while also examining the broader implications and applications of their work. Real-world or embedded course projects build student competencies in engineering design while educating them about the impact they can have as engineers [2]. This approach aligns with the National Academy of Engineering's (NAE) call for a curricular transformation that teaches students how to create meaningful and useful products and services that benefit society. In this context, students must learn to identify and prioritize specifications and to design their solutions to meet customer needs [3]. Furthermore, the NAE report calls for educating engineers who are prepared to take on the challenges faced by an increasingly globalized population.

Academic programs have emerged at universities across the US to prepare students to design technologies for use in developing communities. These include programs at Massachusetts Institute of Technology (MIT), the Colorado School of Mines, Arizona State University, and Villanova University, among many others. For biomedical devices specifically, Rice University offers the Beyond Traditional Borders program, while Johns Hopkins University has created a unique Master's of Science and Engineering (MSE) program aimed at fostering global health innovation through context-appropriate biomedical devices. Collectively, such programs have the potential to make significant contributions to global healthcare challenges through the development of innovative, sustainable and scalable technology solutions. Some of these programs begin by sending students to a developing country for several weeks to gain a firm understanding of the stakeholders and the context. While field-testing and validation of the technologies in developing countries is critical, such literal immersion in the context prior to the commencement of the design phase is usually cost-prohibitive, especially for undergraduate programs.

How can students be prepared to design low-cost biomedical devices for resource-constrained settings in the developing world without the students physically traveling? This article describes a web-based tool called Global Biomedical Device Design (GloBDD) that takes an example-centric approach to address this challenge. It helps students understand how a wide range of factors including cultural, economic, ethical, environmental, and supply chain logistics can influence the design of biomedical devices in diverse environments. Focusing projects on the needs of developing countries provides an opportunity for students to create social impact while simultaneously gaining proficiency in engineering design. From this synergy, students gain an appreciation of the innovation required to make projects low-cost without sacrificing product quality. Moreover, incorporating project application (having real people use the final product) further enhances student responsibility, as the students know their names will be tied to the final product. This can motivate students towards producing exemplary work in a way that grades cannot [4]. Additional benefits of focusing design projects on resource-constrained settings are increases in students' self-confidence, empathy, and commitment to future engagement [5].

There are many obstacles to teaching design to undergraduates. In order to create a useful product, an individual must first discern the true needs of the customer and context in which the product will be used [6]. Intricate details about the resources, infrastructure, and social and behavioral norms of a community can directly impact a product's acceptance and utilization. It can be challenging for undergraduate students to gather such critical information about contexts with which they are not intimately familiar. Designing products for radically different contexts pushes students to search for knowledge and learn to consider factors they previously did not categorize as important. Further, experience is a major factor in successful product design, and thus a lack of experience creates barriers for educators and students alike. Freshman design experiences are useful for introducing students to the principles of design and the variety of processes they can employ over the course of their academic and professional careers [7]. However, it can be difficult to teach students the details of design methods because the research required to effectively create user-centered products is very broad and is difficult to attain within the time constraints of academic semesters [8]. Educators also face the challenge of developing consistent mechanisms to assess open-ended design projects [9]. A final obstacle to teaching engineering design, particularly in bioengineering, is creating projects that are appropriately sophisticated (i.e. not overly complex) for the experience-level of the students.

This paper discusses the Global Biomedical Device Design Tool that was developed to overcome these challenges to biomedical device design education. GloBDD uses customer-validated insights to reveal new and unexpected design solutions and comprehensively explore the "unknown unknowns." The objectives of the tool are: (i) to make students aware of the needs and larger context of the target users, (ii) to encourage students to provide a well-informed rationale supporting every decision made during the design process and (iii) to document concrete design decisions that will ensure the biomedical devices perform as expected in the target developing communities. The tool was integrated and validated in a junior-level biomedical design course at Penn State, where students construct low-cost biomedical devices for rural Kenya. GloBDD can be reviewed at: http://www.globdd.com. This article begins with an overview of the project context followed by a rationale for the tool and description of its content. The paper concludes with findings from an efficacy assessment of the tool.

PROJECT CONTEXT

The Humanitarian Engineering and Social Entrepreneurship (HESE) Program at Penn State integrates learning, research, and entrepreneurship to engage students in the design and launch of technology-based social ventures in developing communities [10]. Students and faculty across all of Penn State's eleven colleges participate in this multi-disciplinary effort. Ongoing ventures include low-cost agricultural technologies such as greenhouses, solar dryers, and anaerobic digesters, a cell-phone based business networking platform, and an innovative science education program, amongst several others. One of the core ventures is a telemedicine system called Mashavu: Networked Health Solutions. Mashavu is an affordable telemedicine system that connects rural Kenyan communities to healthcare professionals [11]. Since May 2011, Mashavu is a cash-positive social venture with six employees (Mashavu Health Workers - MHWs) operating in the Nyeri area of Central Kenya. The Mashavu team is now designing and field-testing low-cost diagnostics that can ultimately be integrated into regular operations with the twin goals of providing health services in rural areas and improving livelihoods of the MHWs.

Several courses with students from all eleven of Penn State's colleges have contributed to the development of Mashavu since 2008. Courses spanning HESE, Bioengineering, Business Administration, and Technical Writing annually focus their syllabi on advancing diverse aspects of the Mashavu venture [12]. Third-year bioengineering students enrolled in Bioengineering 401: "Introduction to Bioengineering Research and Design" are charged with developing the low-cost biomedical devices for the telemedicine system [13]. The enrolled students have limited design experience, having taken only one design course during their freshmen year. The prerequisites for the BioE 401 course include courses in cell and molecular bioengineering and in bio-continuum mechanics, as well as concurrent enrollment in a biomedical instrumentation course. For many students, this course serves as their first introduction into any aspect of developing world cultures. Thus, students enter the semester with only a very general idea of design challenges and processes. Moreover, they lack the knowledge of global cultural and contextual intricacies that influence the designs of appropriate products and services.

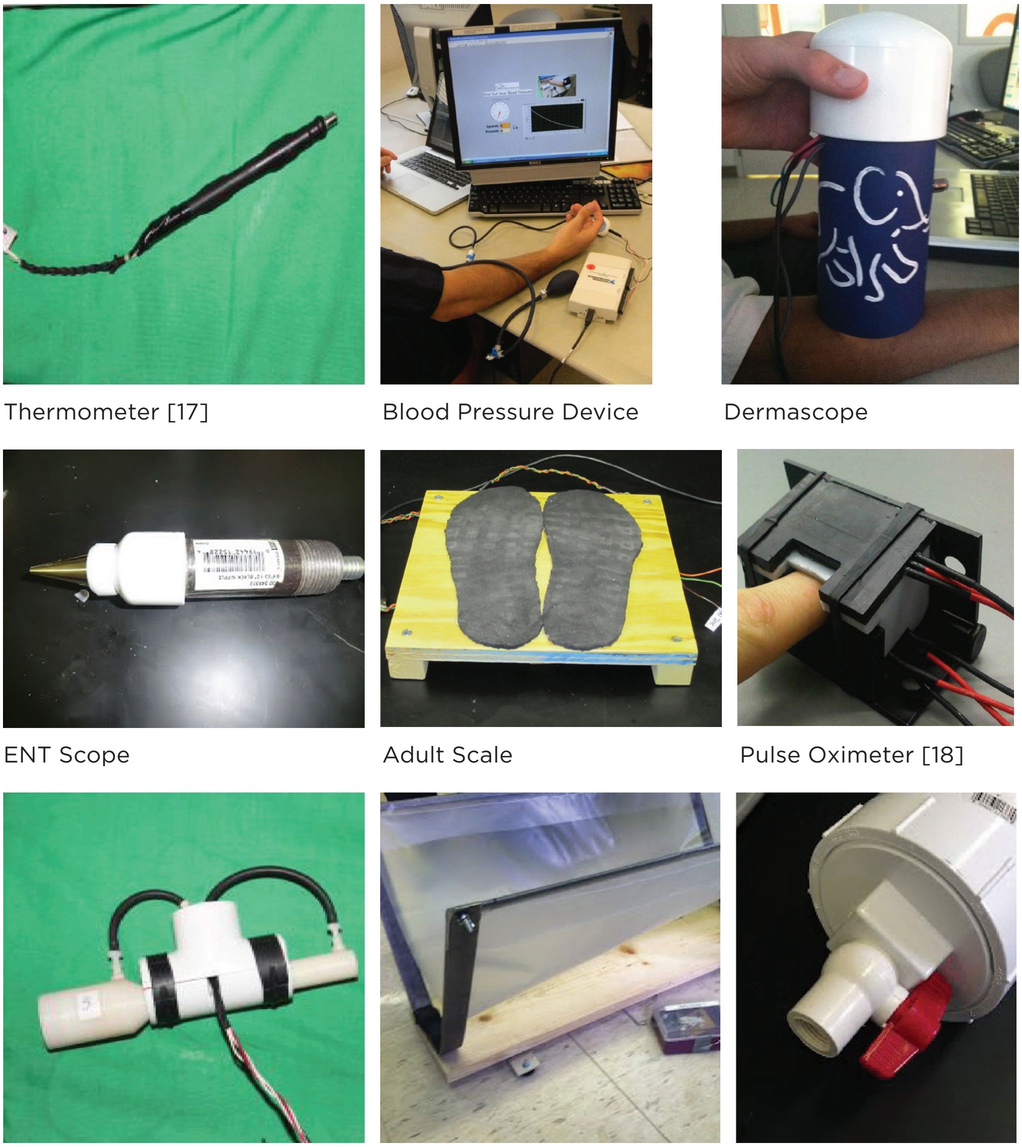
To design biomedical devices, students must possess an understanding of the global healthcare landscape and user characteristics prior to their design attempts [14]. Without this knowledge, students will inevitably face incompatibility between their designs and the contextual needs. Much research has been done to quantify the shortcomings of medical devices in developing countries. One such study found that more than 95% of all medical devices found in public hospitals in developing countries are imported [15]. While major urban areas may have the infrastructure and financial resources to support these complex technologies, rural healthcare dispensaries that service the vast majority of populations do not. Such issues lead to the condition that 96% of the imported devices are unusable within five years [16]. How then can students design low-cost, ruggedized, and context-appropriate biomedical devices that are usable and sustainable in extremely resource-constrained settings? In order to bring this grand challenge to the classroom, the authors created a design tool to guide the creation of low-cost biomedical devices for East Africa.

GloBDD is a webpage template. Each six-member team enrolled in the course uses the template to create their own site, complete with examples about the design decisions made during the creation of their device. This template is intended to be open-ended. Instead of providing for every consideration required in a design decision, it attempts to convey “unknown unknowns” - or aspects of design that students may not have considered. GloBDD contains 19 webpages organized into 6 families. Each webpage delves into a different factor important to the design process by providing examples of other biomedical devices, web resources, and pictures. The tool aids the students’ design approaches and provides them with just-in-time knowledge. GloBDD is described as example-centric because it incorporates over 150 examples of design decisions made about other similar devices. The authors developed and aggregated these examples with input from other Penn State faculty, industry partners, and Kenyan collaborators. Guidelines regarding how to use the tool are available on the homepage.

The goal of GloBDD is to streamline the design process and to alert students to the most pertinent design considerations. Engineering students are required to take heavy course loads in their junior year, and consequently students prioritize how/where to spend their time. At the end of the course, students have the option to travel to Kenya (or other African countries) for three weeks to field-test their devices. Students who intend to travel must become highly invested in project details, as they will be responsible for trouble-shooting any problems that arise while in country. Approximately 20% of the students in the BioE class travel each year.

Students use GloBDD to access relevant information that influences how they design and build medical devices. In spring 2012, students enrolled in BioE 401 used GloBDD to produce devices (Figure 1) that included a thermometer, blood pressure device, dermascope, ENT scope for the Ears, Nose, and Throat, adult weighing scale, baby weighing scale, spirometer, and pulse oximeter. Students used the GloBDD template to create their own website, which they subsequently modified to reflect the design decisions made for their own assigned device.

After understanding the constraints and exploring various design options, students created prototypes and tested them extensively within the class. They also developed their test instruments and sought Institutional Review Board (IRB) approval to conduct further studies in Kenya. At the end of the spring semester, they traveled to central Kenya to test their devices in conjunction with the



Thermometer [17]
Blood Pressure Device
Dermascope
ENT Scope
Adult Scale
Pulse Oximeter [18]
Spirometer [17]
Baby Weighing Scale
Spirometer Calibrator

Figure 1. Biomedical Devices Produced by Student Teams.

entire Mashavu telemedicine system. During the trip, students worked closely with staff from the Kenyan Ministry of Health and Public Sanitation and other partners to evaluate the functionality of the devices. Recommendations were brought back for subsequent teams. The blood pressure device, thermometer, adult weighing, scale and spirometer were all tested and found to have acceptable margins of error as compared to commercially available devices [17].

GLOBAL BIOMEDICAL DEVICE DESIGN TOOL RATIONALE & OBJECTIVES

When creating products for the developing world, designers often struggle to grasp what the true requirements of the context entail because they are biased by the assumptions of the culture in which they live. The developing world has a unique set of challenges, and by addressing the various constraints and using them to drive the design process, products are more likely to meet the needs of the target population and thus be competitive and useful. However, design education is not straightforward; learning to "anticipate the unintended consequences emerging from interactions among the multiple parts of a system" is heralded as a great challenge for students [2]. In many cases, design is taught as a question-driven process, with inquisitive questions leading students to discern what characterizes an acceptable solution [19]. Students must not only learn the value of asking questions, but also how to ask the right questions in order to optimize their design experiences [20].

In lieu of asking questions, students often try to incorporate features of similar designs or draw inspiration from prior knowledge and experiences. Doing so is an essential step in the process of making decisions and moving towards a final product [21]. Examples provide a starting point for design exploration, and help designers to connect theory and practice. Examples also provide a foundation for questioning, an important factor to ensure that the "right" questions are asked. In addition, by knowing how others have solved issues similar to their own, engineers become more adept at designing within constraints [22]. One limitation of employing examples is that engineers quite often become fixated on a previous solution and struggle to move beyond it [23]. This challenge, referred to as design fixation, is particularly common for students who have fewer experiences on which to base their ideas compared to those who have worked in the field extensively [21]. GloBDD helps students to overcome design fixation by including a wide range of examples that are derived from diverse real world situations.

GloBDD is a website that incorporates a large database of examples about biomedical device design and related fields. It is intended to provide students with ample material to assist in generating design ideas and valid assumptions and to trigger their imagination. Students who have only seen medical devices within the US healthcare sector need exposure to the developing country context for which they are designing through the course. For several years, the instructors tried to convey contextual requirements and nuances via lectures with PowerPoint presentations, but that strategy proved ineffective. While students gained a better understanding of the broader context, they were not able to internalize how the context influenced their design decisions until they arrived in-country for testing. In order to enhance the students' impact, the authors sought to expedite student learning while still in the classroom. Thus GloBDD, a compendium of examples and lessons, was built to serve such a purpose. The goal was that this diversity of approaches and examples would preempt design fixation. While other tools like IDEO's Human-Centered Design Toolkit place a greater emphasis on product implementation, GloBDD focuses primarily on the product design process [24]. Contextual details provide radical opportunities for innovation and incorrect assumptions or priorities may hinder an engineers' openness to inspirational insights [25]. To combat this and expand their knowledge, students actively search the internet to seek out information that they believe can aid their ideation [26]. However, the endless information can leave students uncertain of what it is they are researching and can open them to design fixation. Design tools can guide students to usable web resources in order to ensure they neither search in futility nor become fixated on a single trajectory [27]. GloBDD is similar to Appropedia, a collaborative compendium of examples related to appropriate technology [28], which has been used to teach principles of sustainable design at other universities. However, unlike Appropedia, GloBDD focuses on a specific challenge: constructing context-driven biomedical devices. The objective of the Global Biomedical Device Design Tool are to:

1. Provide students with starting points for design space exploration by making them aware of pertinent factors for consideration.
2. Enable students to articulate a well-informed rationale supporting every decision made during the design process.
3. Facilitate students' structured documentation of design decisions and design evolution over time.

GloBDD contains a systematic series of questions and real-world examples that incorporate an expansive list of concerns ranging from social and cultural to structural to electrical factors. Many of the examples pertain to East Africa and the Mashavu telemedicine system, as they are most relevant for the students. However, the tool also provides general examples that can be applied to any context. For each question asked, resources are provided to aid in design exploration, and guide engineers to make effective trade-offs and reach an equilibrium between various factors. (For example, reaching a balance between price point, materials used, and sustainability concerns for the specific users and their context). Resources include case-study examples, journal articles, and links to other websites, online videos, and photographs of other context-driven designs. Additionally, the resources serve to demonstrate how a specific choice can have implications for other aspects of a design. From a design standpoint, it is invaluable to be able to see the interconnections between components, and to see the connections between a biomedical device and the larger context (social, cultural, economic) in which it will be deployed.

GLOBAL BIOMEDICAL DEVICE DESIGN TOOL DESCRIPTION

GloBDD consists of 19 sets of design factors (Figure 2) clustered in six categories. These categories were chosen based on the ideas of Penn State faculty and students who collectively have

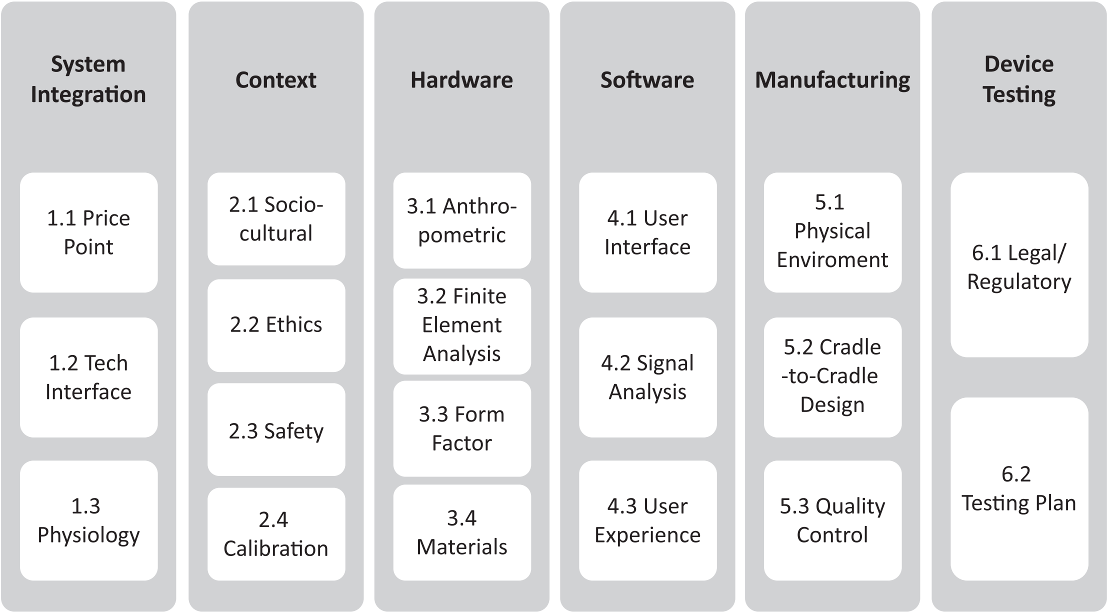


Figure 2. Design factors explored by the Global Biomedical Device Design Tool.

decades of experience working in developing communities. Within the tool, categories are grouped according to student roles. Though students are expected to contribute to all aspects of a project, one student per team was ultimately responsible for a design category. These were termed Context Lead, Hardware Lead, etc. The order in which the factors are presented in this paper does not correspond to order of class discussions.

The next section discusses each of these six categories and their sets of design factors with specific examples drawn from GloBDD. Examples from each of these sub-categories are presented on a webpage.

System Integration

System Integration revolves around ensuring that the overall product design meets all necessary functional and non-functional requirements, works well with the Mashavu system, and is affordable and appropriate for users in the specific context. System integration encompasses the technical interface, price-point management and physiological factors.

Price Point **[**https://sites.google.com/site/bioedevicedesign/price-point **]**

Affordability is a key factor in determining whether or not a device will be sustainable in the developing world. The cost of the product is influenced by sensor choice, materials, number of wires required, and necessary signal processing. However, a balance must ultimately be struck between cost reduction and usability or quality of measurements.

Example: If a design incorporates a strain gage sensor, then a Wheatstone bridge, op-amp and external power supply are also necessary. The cost of the entire sensing system must be considered in cost analysis. An alternate approach might be to use a different sensor like a load cell or a data acquisition device with higher precision that can measure smaller signals and eliminate the need for the amplification circuitry.

Tech Interface **[**https://sites.google.com/site/bioedevicedesign/tech-interface **]**

The tech interface (Figure 3) defines how the hardware and software are connected and will work together. Poor or non-existent grounding is a key interface issue, and is one of the most common problems leading to device malfunction. Other areas discussed in this category include amount of power drawn, sampling rate requirements and the selection of data acquisition devices.

Example: Filtering is used to remove unwanted noise from a signal. Power line hum is caused by magnetic induction, ground loops or poor impedance matching, among other reasons, and can compromise the accuracy of biomedical signals. In the US, a 60 Hz power supply is utilized, while Africa and Asia use a 50 Hz power supply. Thus, a low pass filter with a cutoff frequency below 50Hz could be employed to remove noise from the signal. Depending on the severity of noise and the sensitivity of the measurement, the filtering can be performed through either hardware or software. The hardware solution is likely to be better but more expensive.

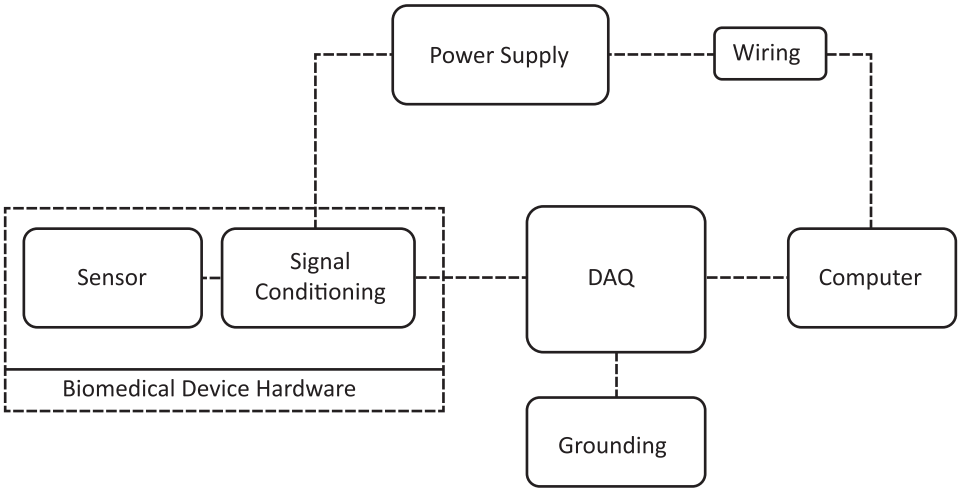


Figure 3. Tech Interface General Schematic.

Physiology and Clinical Indications [https://sites.google.com/site/bioedevicedesign/physiology]

Physiology dictates the type and range of measurement a device must obtain. Sometimes, there are several ways to obtain the biomedical measurement. The engineer might access different body parts, or different physiological processes to get to the same vital sign and have their device take a reading accurately.

Example: If an individual were to take their oral, rectal, and axillary (under-arm) temperatures they would receive three different measurements, as different parts of the body have different average temperatures. Axillary measurements are often lower than the body's true temperature. If a thermometer were to be implemented in a region with higher likelihoods of communicable diseases, it may be better to design the device to accurately measure axillary temperatures in order to lower the risk of disease spread. A conversion factor would have to be utilized to adjust the resulting temperature to true body temperature in order to properly assess a person's health status.

Context

Contextual requirements focus on the device's ability to operate and sustain in specific environments. For GloBDD, there is an emphasis on resource-constrained environments in developing countries.

Socio-cultural Factors [https://sites.google.com/site/bioedevicedesign/sociocultural]

Socio-cultural factors are influences derived from the customs, traditions, perceptions and beliefs of an individual's culture and can be a key determinant in whether or not a person even agrees to seek care and use the devices. To increase the usability of a design, a device should fit seamlessly into societal norms and avoid resembling anything with a negative social connotation, disrupting gender roles, or causing privacy issues.

Example: It is typical for women to keep their children tightly wrapped in a lot of fabric to keep them warm and protect them from the physical environment. If a parent refuses to remove the baby's clothes how does that affect the weight measurement? How can you design the scale to be something a parent would trust to put their baby into or how could you calibrate the scale differently to potentially include the weight of the clothes?

Figure 4. Bundled child in Kenya.

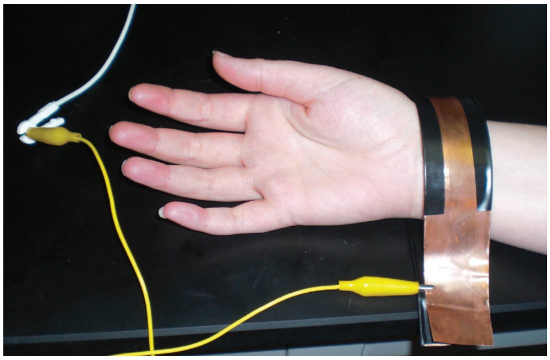
Ethical Issues **[**https://sites.google.com/site/bioedevicedesign/ethical-issues**]**

Design decisions can significantly impact the lives of users and thus it is important to consider potential consequences, intrinsic values, and complex relationships between stakeholders in the design process. Students examine realistic case studies by employing an eight-step review process adapted from one developed by the HESE program [29]. The process entails determining stakeholders, identifying the most salient information, assessing potential consequences and analyzing alternative courses of action. After analyzing an ethical scenario, students must decide upon a course of action, because in the real world, the situations cannot be left unsettled.

Example: In 2002, the World Health Organization (WHO) launched an initiative to promote injection safety through the use of auto-disable syringes in communities with high infectious disease prevalence. Auto-disable syringes prevent the risk for spreading disease by locking after a single use, but cost 20% more than a standard syringe, making it potentially unaffordable for some target users [30]. WHO engineers and physicians decided that it was unethical to continue to use syringes that propagated disease and the safety features of auto-disable syringes justified the raised price point.

Safety Issues **[**https://sites.google.com/site/bioedevicedesign/safety-issues**]**

To gain the trust of the user, the safety of a device must be sufficiently documented and quantified when appropriate. Ease of sanitation, a low risk of physical injury, minimal electrical currents and electromagnetic emissions, all contribute to the sustainability and efficacy of devices. Without regulatory controls, patients and device operators have the potential to be harmed or be vulnerable to legal challenges.



Example: An ECG measures voltage across the body, and hence runs the risk of giving the patient an electric shock. The American Heart Association contends that a maximum of 10uA should flow through a patient-device lead at any given time, even when the device has an error (such as a failed component, disconnected ground wire etc, Current limits are necessary because sending a high current through the body can lead to ventricle fibrillation of, at extreme levels, patient death. Currents as low as 35uA have the potential to compromise the heart's functionality.

Figure 5. Low-cost ECG developed by a 2011 Student Team.

Calibration **[**https://sites.google.com/site/bioedevicedesign/calibration**]**

Calibration against a known value is necessary to define the accuracy of a device. Without doing so, there is no way to prove that the device is providing the desired measurements. Finding an available and inexpensive means of device calibration can be quite difficult in the developing world, but having a standard calibration process is critical, as is defining excusable amounts of error.

Example: A fixed mass is needed to calibrate weighing scales. However, weight standardization is unreliable in developing communities. Ten 5-kg bags of flour could be purchased from the same store and all weigh different amounts, making them difficult to use as a means of calibration. Plastic bottles are essentially available everywhere and when filled with water, which has a known density, could serve as an accurate calibration tool for a weighing scale.

Hardware

The hardware consists of all components that comprise the body of the device and protect the chosen sensor.

Anthropometric Requirements **[**https://sites.google.com/site/bioedevicedesign/anthropometric**]**

Anthropometry is defined as "the science of measuring the human body and its parts and functional capacities" [31]. Knowledge of the anthropometric data of a population is critical for bioengineers as it allows designs to be tailored to a specific audience.

COMSOL Multiphysics Finite Element Analysis software **[**https://sites.google.com/site/bioedevicedesign/comsol-model**]**

COMSOL Multiphysics is a finite element analysis software program that provides the means to model engineering designs and simulate potential failure modes. The program allows exploration of

Example: Over the past decade, the occurrence of hypertension has been rapidly rising in Kenya. Thus, in designing a blood pressure cuff, the upper measurement limit had to be expanded in anticipation of numerous readings in extreme ranges. Furthermore, hypertension has been liked to growing rates of obesity, particularly in urban towns in sub-Saharan Africa. Standard and large cuff sizes are necessary in order to accurately measure the blood pressure of the general population, which presumably has a wide range of arm circumferences.

Figure 6. Blood Pressure Measurement in Kenya.

various assumptions, design geometries and boundary conditions, and consequently users are able to visually and quantitatively analyze the implications of different design decisions.

Example: Designers of a thermometer are trying to decide between using brass or copper to encase the temperature sensor. COMSOL is used to determine which material and device geometry will lead to the shortest measurement reading time. Ultimately, a hollow brass tube is chosen to encase the sensor and the total time to reach steady state temperature dropped to 48 seconds. The measurement time could also be shortened by exposing the sensor; however that compromises the durability of the device in the harsh environment of Kenya.

Form Factor **[**https://sites.google.com/site/bioedevicedesign/formfactor**]**

Form factor refers to the physical geometry (size and shape) of the device. The form factor impacts the functionality, portability, durability, and credibility of the device. Establishing device credibility is a key factor in ensuring that people will not be in any way intimidated or scared to use a product. If a spirometer resembles a handgun would a person want to place the device in his or her mouth, or would be they be skeptical solely as a result of the device appearance?

Example: In developing a low-cost infant warmer, Embrace Global (a non-profit organization) wanted to move away from traditional incubators. They were too expensive, fragile, not easily cleanable, and they required a power supply. Donated incubators were being used as cribs in the developing world because of lack of instructions or resources to operate them. Embrace Global modeled their design off of another common warming device: a sleeping bag. The infant warmer tightly wraps a child and has a pocket that holds a wax heating pad that can be heated using electricity or by warming it over a fire [32].

Materials **[**https://sites.google.com/site/bioedevicedesign/materials**]**

Material selection directly influences the robustness, longevity, and usability of a device. In designing for the developing world context, cost, quality and availability of materials must be considered. Additionally, materials must be examined from a manufacturing standpoint and ease of use for construction and consistent function must be determined. Plastics are commonly available, come in virtually every shape and size and are extremely low-cost. However, they also have many failure modes, and it is often challenging to find plastic parts with standard sizes in East Africa. On the other hand, a material such as titanium is lightweight, strong, but more expensive than traditional steel or aluminum.

Software

Mashavu devices interface with the computer via a LabVIEW Virtual Instrument (VI) that captures the desired measurement and displays it on a front panel that is usable by both the patient and the operator. The LabVIEW graphical programming environment is used to develop the software routines

Example: An electronic stethoscope was composed of a commercial aluminium stethoscope chest piece, commercial tubing, a microphone and microphone extension cord, heat shrink tubing and isolation material. An aluminium chest piece was chosen because of its availability, reliability and low-cost ($3) relative to a stainless steel chest piece ($20). Although the stainless steel chest piece produced better sound than the aluminium one, software better sound than the aluminium one, software filtering and amplification was able to compensate for the quality difference, making the aluminium chest piece the optimal choice. However, if the device were to be deployed in a noisy environment, the stainless steel chest piece may have been the only option due its superior sound conduction qualities.

Figure 7. Student-Designed Stethoscope in 2011.

necessary for data acquisition, display, analysis, and calibration of biomedical devices. However, these design factors are relevant for any software platform that is employed for the biomedical devices.

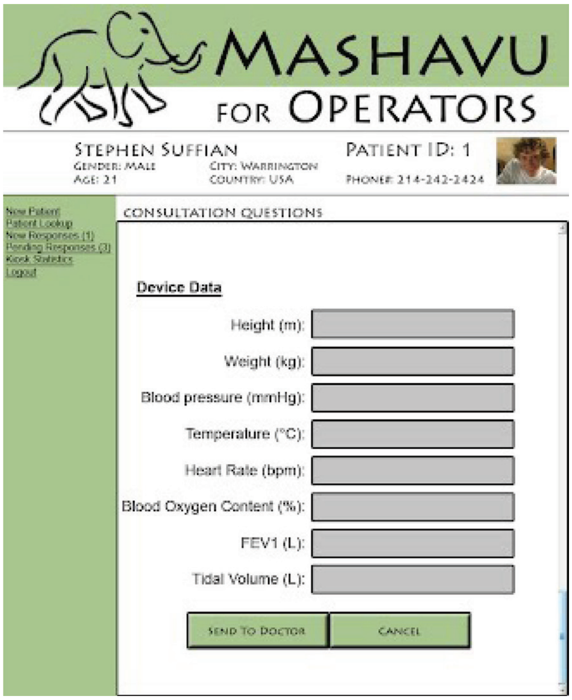
User Interface (UI) **[**https://sites.google.com/site/bioedevicedesign/user-interface**]**

The user interface guides an individual through the software and facilitates smooth operation of the device. It must be intuitive and easy to navigate so that users feel comfortable operating it. Often, symbols and icons that are well-understood metaphors in the US do not have corresponding meaning in other contexts. Color choice, means of organization, and units of measurement are all examined in the UI category.

Signal Analysis **[**https://sites.google.com/site/bioedevicedesign/signal-analysis**]**

When using an inexpensive sensor and minimal circuitry, signal analysis on software becomes the most important factor in obtaining an accurate measurement. It is essential to pick the appropriate algorithm and provide embedded comments so that other developers can understand the logic and debug it if necessary.

Example: If used in a noisy environment, electronic stethoscopes require additional filtering to obtain a sound recording with all the frequency and amplitude characteristics of a heartbeat or lung. This signal analysis can be accomplished either by investing in more expensive hardware to ensure a better quality measurement, or by filtering that can be performed in software. One means of isolating



STEPHEN SUFFIAN
GENDER: MALE
AGE: 21
CITY: WARRINGTON
COUNTRY: USA
PATIENT ID: 1
PHONE#: 214-242-2424

Figure 8. Mashavu User Interface.

Example: The user interface must be clear and easily understood. If the front panel contains too many objects or has distracting mixture of color and text, the end users might not use the application properly of might not receive important information from the data. White space and alignment are probably the most important techniques for grouping and separation. The more items that your eye can find in a line, the more cohesive and clean the organization seems. When items are on a line, the eye follows the line from left to right or top be bottom. This is related to the script direction. Although some cultures might prefer items arranged from right to left, almost all follow a top to bottom convention.

the desired heart or lung frequency spectrum via software is to utilize a Butterworth bandpass filter, which consists of a flat pass-band. Physiologic differences lead to heart sound frequencies varying from person to person. The type of filtering (hardware or software, type of filter, filter order) will ultimately dictate the quality of the signal received and the cost of the device

User Experience **[**https://sites.google.com/site/bioedevicedesign/user-experience**]**

Unlike the User Interface (UI), which consists of the computer screen a person sees, the user experience is the complete series of interactions that an individual will encounter while using a system. Designers must think about how each step of that process can be enhanced to ensure maximum enjoyment, respect, safety, satisfaction and effectiveness.

Example: An organized yet comprehensive Stethoscope UI would exhibit a live graph indicating breathing or heartbeat in real time. Meanwhile, the practitioner can record useful filtered stethoscope sounds, save the collected data to a file, and then play the sound back on the speaker, post-measurement, for the patient to hear. This engages the users, and provides them with immediate feedback relevant to the status of their own health.

Manufacturing

The way in which the device will be mass-manufactured and moved from the design stage to the product stage directly impacts the cost and functionality of the device. While the focus of the tool is not on design for mass manufacturing because students will not reach this stage, it is essential to consider manufacturability factors early in the design process.

Physical Environment **[**https://sites.google.com/site/bioedevicedesign/physical-environment**]**

Devices must be usable in the specific environment in which local citizens will maintain and operate them. This requires research on weather patterns, temperature swings, humidity levels, quantities of dust, and changes in atmospheric pressure. For example, dust levels in parts of sub-Saharan Africa necessitate close attention since they can severely limit the life of the device. Additionally, medical devices will inevitably be jostled during transportation along bumpy roads, thus requiring attention to be paid to securing wires.

Example: Dust exposure is a significant problem for any devices containing Velcro. After approximately one year of frequent use, the durability of the Velcro deteriorates. With dust particles building up and catching in the Velcro, the dust only accelerates the deterioration of the Velcro. In constructing a blood pressure cuff, the tradeoff of not utilizing Velcro was an inability to sufficiently tighten the cuff. Since that was not an option, the cuff must be secluded from the environment when not in use.

Additionally for the blood pressure cuff, dust can cause problems with the output flow of the air. The tip off of a dispensing needle was cut off and connected to a valve port to output air flow during the deflation of the device. The diameter of the dispensing needle is 0.1mm. The size of atmospheric dust particles ranges from .001 to 20 microns in diameter. Over time, build up of atmospheric dust particles to the output valve could disrupt airflow. To prevent this, the dispensing needle should be unscrewed from the cap, rinsed and dried via air from the mouth and screwed back on. This cleansing process should be repeated at the end of each day's use.

Cradle-to-Cradle Design **[**https://sites.google.com/site/bioedevicedesign/cradle-to-cradle-design**]**

Unlike cradle-to-grave design, where products follow a linear path and are eventually disposed of, cradle-to-cradle design aims to create products with circular lifecycles. Once products are no longer usable for one purpose, all component parts can be broken down, reprocessed or remanufactured, and made to be productive into another domain [33]. By taking the entire lifecycle of a product into consideration, one can ensure that the system's materials are able to be adapted for use with other future systems.

Example: For baby weighing scale, a cradle is needed to hold the infant. Instead of using a plastic bin, a sisal basket could be used. Sisal, also known as hemp, is an organic material readily available in resource-constrained environments. Though there may be difficulty in sanitizing the cradle, the device would be able to be locally produced and repaired as a result of material familiarity. Additionally, once the basket needed to be replaced, the hemp could be recycled within the community.

Figure 9. Sisal Weighing Scale.

Quality Control **[**https://sites.google.com/site/bioedevicedesign/quality-control**]**

Designing for manufacturability means minimizing labor, materials, and the time of assembly without sacrificing the quality of the product. In doing so, the total cost of a device decreases while the efficiency of its production increases.

Example: Hand-made circuit boards are often difficult to replace and so the manufacturing process can be simplified if the circuit is prefabricated. Prefabricating the circuit will avoid the hassle of locating all of the necessary circuit elements, soldering them to a circuit board and identifying a locally-available individual with the background to perform the tasks.

Device Testing

Testing plans must be devised and implemented to examine accuracy, precision, repeatability, reliability, hygiene issues, mechanical problems, failure modes, shock resistance, calibration needs, maintenance needs, functionality in a dusty environment, and other indicators of the success (or failure) of the device.

Legal/Regulatory **[**https://sites.google.com/site/bioedevicedesign/legal-regulatory**]**

Before the medical device is used in a clinical setting, it must be approved by several regulatory entities. When working in a country other than the US, the various governing entities may have regulations that are more or less stringent than what a designer is used to, and it is important to determine as early as possible what approvals are necessary.

Example: In order to be able to operate biomedical devices outside of the US, designers must gain FDA approval, which can take 6 months to several years, or certify that their products are exempt from FDA regulations. If the device is exempt from FDA approval, engineers must still ensure that the device adheres to all local laws. When designing for a foreign country, the designers might be required to confirm to all regulations in their home country as well as the foreign country.

Experimental Testing Plan **[**https://sites.google.com/site/bioedevicedesign/experimental-testing-plan**]**

Beyond testing the above-mentioned parameters, tests must also be done to determine the usability of the devices in accordance with the overall system, the value created, ethical challenges encountered, liability, and educational needs of the stakeholders.

Example: To test the software component of the thermometer, the voltage output by the device circuit is measured with a voltmeter, and then compared to the reading by the LabVIEW program. The temperature is compared to readings from a calibrated commercial device. A test program can be developed to confirm functionality at any time, and can even be shipped with the final software to facilitate maintenance and repairs of the device after deployment.

ASSESSMENT METHODOLOGY

To understand the benefits of using GloBDD in Bioengineering 401, a research study was conducted over the course of the semester. The class met three times per week for 15 weeks. For the first six weeks of the semester, the class defined the overarching problem, gained an understanding of the context, reviewed 3D modeling software program skills, and learned the fundamentals of LabVIEW. During this time, students also worked in teams to analyze a prototype developed during the previous year. While students were introduced to GloBDD in Week 1, they did not have to make any design decisions until after Week 6. The delay allowed students five weeks to brainstorm their own solutions without feeling compelled to commit to specifics. After this exploration process, students spent the remaining weeks making and explaining their initial decisions with respect to each design factor. They documented these decisions and their rationales on the GloBDD website at a rate of two factors per week, in accordance with the design stages. By the end of the semester, students were required to have all design decisions documented in the appropriate space on the GloBDD website. The design decisions and rationales described by each team were analyzed by the authors, one of who was the course instructor, to determine the efficacy of GloBDD as an instructive tool. The course instructor did not partake in the student interviews.

The assessment sought to examine three hypotheses. Each was assessed by a different mechanism as detailed below.

Hypothesis A: While creating biomedical devices for resource-constrained environments, examples provide students with starting points for design space exploration by making them aware of pertinent factors for consideration.

This hypothesis sought to validate the use of examples as a fundamental component of the tool.

All nine teams met for one hour mid-semester for a semi-structured interview with the authors. The results of these interviews were transcribed and coded to evaluate the students' design processes.

Teams were asked to explain the design process they followed prior to Week 6 of the semester. Further questions included (i) What information was provided about your device at the beginning of the semester? (ii) What did you want to change about your device? (iii) How did you brainstorm ways to bring about desired changes? (iv) What progress have you made in making changes thus far? (v) From where did you draw inspiration for your ideas?

Hypothesis B: GloBDD enables students to articulate a well-informed rationale supporting every decision made during the design process.

During the last scheduled BioE 401 class period, student teams were asked to discuss, and write answers to, the following questions: (i) Give five examples of how you used the tool to develop your project (ii) Give five suggestions of ways to improve the tool (iii) What is the value of documenting your design process?

Hypothesis C: GloBDD facilitates structured documentation of design decisions and design evolution over time.

Each team used the GloBDD website as a template to create their own website detailing all aspects of the design. Each rationale the team provided in a "design factor" section of the website (Form Factor, Cradle-to-Cradle etc), was then scored according to the following rubric. Students were encouraged to describe any and all rationales that were relevant to their device.

i. 0 points – design factor was not taken into consideration or was undocumented
ii. 0.5 points – design factor seems to be thought about but effort to document its role was minimal or nonexistent
iii. 1 point – a convincing rationale was found on the website that showed the design factor was taken into consideration and, when relevant, is reflected in a design decision

Every example generated by the students on their team's page was assessed using the above rubric. For most of the design factors, students generated multiple examples. The points earned for each example contained on a page were added up to give a total score. The scores for each design factor were averaged across all teams in order to better understand which factors students were able to apply to their own device.

RESULTS AND DISCUSSION

This section discusses how students enrolled in BioE 401 integrated GloBDD into their design process and how they benefitted from (or were unaffected by) the tool. A total of nine six-member teams participated in the study during the spring of 2012. The results of this IRB-approved study are all preliminary indications. Larger conclusions would mandate a larger sample size.

Tool Provides a Starting Point for Design Space Exploration

The first aspect of the study sought to examine how students engaged in design space exploration before utilizing GloBDD. This is an important aspect to analyze because the way in which students brainstorm impacts the final product they make. In a semi-structured 1-hour interview (approximately six weeks into the semester), teams were asked to explain the design process undertaken thus far. While the teams knew of the GloBDD, no teams were actively using it as of yet. Further questions beyond the ones listed above were asked according to the flow of the conversation.

Most teams cited very similar sources of inspiration with little variation between the teams, as shown in Table 1. Researching commercially-available devices was the most common method for gaining knowledge about how to improve the designs of the virtual instrumentation-based designs. All teams also recognized the importance of brainstorming, and repeatedly stated that the projects would not advance without group input. Every interview was characterized by vague responses and a lack of detail regarding what specifically had contributed to the genesis of an idea. Additionally, each idea source was seemingly inchoate, and the team required more information before they could transform their ideas into design decisions.

1. *Researching commercially available devices that are similar: "Commercially available devices allowed us to really understand the foundation of our design and how to build it further."*

Teams' research allowed them to understand the basic operations of devices on the market. They also stressed the importance of discovering what hospital standards exist for their particular device. Further, they looked at commercially-available products in an attempt to find aspects they could adapt to be appropriate for their purposes. However, no team discussed the relationship between the devices and the physiological processes from which measurements are derived; nor did teams mention how their device could be used to assess disease states. Many students delineated

1. Researching commercially available devices that are similar (9/9 teams)

2. Engaging in team discussions; group brainstorming (9/9 teams)
3. Considering contextual factors and design constraints (8/9 teams)
4. Examining the devices made by teams from previous years (7/8 teams)*
5. Thinking about personal experiences (7/9 teams)
6. Other sources of inspiration (7/9 teams)

*All but one device had been made in previous years.

Table 1. Sources of Inspiration Prior to Use of GloBDD

the tradeoffs they felt they would face (i.e. cost vs. accuracy), though they could not specify which components of the commercial device raised its cost.

2. *Engaging in team discussions; group brainstorming: "It definitely helped when we got together as a group to talk about the pros and cons of solutions for the problem presented to us."*

All teams valued group discussions and input from a large number of individuals. Over half of the teams agreed that the projects would be impossible to complete individually. Collaboration within the group allowed for the production of design ideas and subsequent refinement. Six group members with diverse backgrounds in terms of past experiences and gender provided a strong sounding board for idea assessment. However, despite weekly or semi-weekly conversations about the project and its development, only one team had written down a list of tasks they wanted to accomplish. Without writing down specific problems, everything discussed remained abstract, and very few concrete decisions had been made across all 9 teams.

3. *Considering contextual factors and design constraints: "…[We] need to know about the culture and the context to verify that aspects of our designs will be appropriate where we are implementing the device."*

Due to the international nature of the project, almost every team mentioned that culture and context would impact their design. They wanted to create devices that could be seamlessly integrated into society and to avoid any components that would prevent usage by the target customers. Since no students had previously traveled to Kenya or designed products for developing communities, they lacked the knowledge of how to integrate cultural constraints into a design. As such, the students only used general comments about context-driven design such as striving for cost-effectiveness and cultural appropriateness. The mechanisms for achieving such goals were absent.

4. *Examining the devices made by teams from previous years: "Putting together last year's prototype and using it allows you to figure out what's easy and what's hard about it."*

In the first week of the semester, each team was provided with a drawer containing past teams' prototypes and excess materials. The ENT Scope was a new device, and therefore had no previous devices or materials to work with. From the onset, teams were encouraged to work with the devices and uncover their strengths and weaknesses. The students derived value from this exercise because it showed them the design priorities first-hand and what changes were critical for success. Additionally, students were given access to the websites of previous teams' who had also used GloBDD. Despite having access to this resource over half of the teams had yet to peruse this documentation at the time of the interviews. Those who had not done so were unaware of the rationale behind certain aspects of the design.

5. *Thinking about personal experiences: "I think [ideas] come from past experiences, a combination of past teams' and our personal past experiences."*

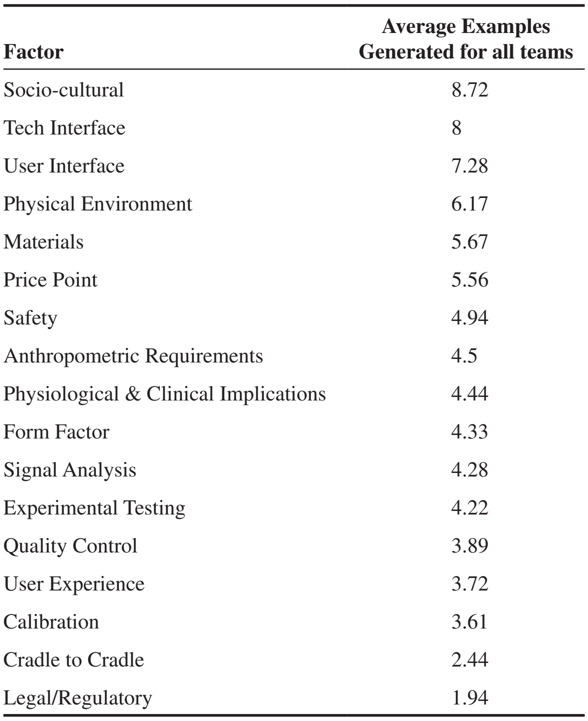
Though every student in the class majored in Bioengineering, each member of the team had a differing skill-set as a result of focus within the major. (Each student in Bioengineering is required to focus in mechanical, chemical, electrical, or materials science engineering.) The class teams were assigned semi-randomly resulting in a mix of males and females and student concentrations. This allowed members to contribute a variety of experiences to the design process. While attempting to generate ideas, the students drew on their individual experiences to find applicable inspiration for their current product. Most teams acknowledged that their previous interactions with primary healthcare influenced the experience they wanted to create around their device. Similarly, teams were eager to find objects in everyday life that could provide them with inspiration and subsequently shape a particular aspect of the design.

6. *Other sources of inspiration: "Mentors are important also for idea exchange; We're going to go to a camera store to try and discuss options for improvement."*

Because each team represented a diverse array of students, sources of inspiration across all teams were not entirely uniform. Several teams mentioned that their ideas came from their determination to generate them, as they knew their attachment to this project would not end on the last day of the semester. Teams also looked to the curricula of other courses in which they were enrolled (such as Biomedical Instrumentation) to help identify areas of device improvement. Finally, teams cited engineering analysis software programs as helpful for allowing them to verify the plausibility of their ideas. Many students had questions about what aspects of their device could be modeled, and what other programs could serve this purpose.

Design Tool Efficacy

The goal of GloBDD is to facilitate the context-driven design of biomedical devices. GloBDD currently contains over 150 examples from which student-engineers can draw inspiration. Routine use of the GloBDD website halfway through the semester helps students explore design considerations, draw inspiration, and formulate rigorous rationales for design decisions. Though having students interact with the tool earlier may have been beneficial, delaying use allowed us to compare student competencies before and after use. Students are instructed to read the examples provided and use them to uncover the specific requirements they need to satisfy for their device to be accepted into the Kenyan context. As students incorporate issues covered by the tool into their own device, they are tasked with documenting their design decisions. Each team ultimately uses the GloBDD website as a template to create their own website detailing all aspects of the design. For the purposes of this assessment, the authors and a graduate student in electrical engineering with four years of



Factor	Average Examples Generated for all teams
Socio-cultural	8.72
Tech Interface	8
User Interface	7.28
Physical Environment	6.17
Materials	5.67
Price Point	5.56
Safety	4.94
Anthropometric Requirements	4.5
Physiological & Clinical Implications	4.44
Form Factor	4.33
Signal Analysis	4.28
Experimental Testing	4.22
Quality Control	3.89
User Experience	3.72
Calibration	3.61
Cradle to Cradle	2.44
Legal/Regulatory	1.94

Table 2. Examples generated by students per design factor.

experience working in developing countries but no previous involvement with GloBDD reviewed team websites. Every student rationale contained on the website that discussed a specific aspect of their design was scored according to the aforementioned rubric.

After coding all nine websites, the points accumulated for each design factor were summed across the teams and then averaged (Table 2) in order to determine which factors the students were able to understand and subsequently apply to their own designs. The rationales provided for some categories, such as Physiology and Clinical Implications, were sourced from Wikipedia and Google searches; however this is often sufficient for students to understand the broader impacts of their device. Further, providing minimal rationale does not necessarily imply a poor understanding of a factor. Both Cradle-to-Cradle Design and Legal/Regulatory Compliance Issues are difficult to integrate into a design within the time and financial constraints of the academic semester. The value in these categories is introducing students to concepts that will likely be essential later in their careers. COMSOL Multiphysics finite element analysis and Ethics were both excluded from analysis. In these categories, GloBDD provides instructions for a homework assignment instead of examples.

1. Introduced Unforeseen Design Factors (9/9 teams)
2. Used Previous Websites as a Starting Point (7/8 teams)*
3. Organized Ideas (9/9 teams)
4. Facilitated Design Process (6/9 teams)

* All but one device had been made in previous years

Table 3. Impact of GloBDD in Project Development.

Another assessment was conducted at the end of the semester. Though it would have been ideal to conduct follow-up interviews with each team, due to the time constraints it was not possible. In lieu of this, each team completed a survey for the researchers to gain a clearer picture of the impact of the design tool on the students' design processes.

Table 3 shows the impacts of the design tool as described by the students. Each impact is described in more detail below.

1. *Introduced Unforeseen Design Factors: "The Design Tool helped us to think of design processes that we wouldn't normally have thought of, like some of the socio-cultural factors and ethical issues."*

All teams described how GloBDD helped them discover design considerations they previously had not considered. Learning about "unknown unknowns" is one of the main functions of the design tool. With minimal design experience, students need to be introduced to topics as they become relevant over the course of the semester. For example, teams said that the Physical Environment page helped them realize they must protect their sensors from dust. The Anthropometrics page ensured teams' designs used appropriate dimensions for the target user. Additionally, the Calibration page gave suggestions on how to calibrate a camera and how to use local resources to achieve device accuracy. Other categories with examples especially foreign to students include the Socio-cultural, Physiological Indications, and Form Factor. According to one student, the tool contributed, "good examples of items that could have easily been disregarded or forgotten, like Safety and Tech Interface." While not all students applied an example to their design correctly, there is still value in introducing all factors relevant to the context.

2. *Access to Previous Team Websites Served as a Starting Point for Decisions: "Using the website from last year helped us determine what the flaws were in last year's design. We used last year's information to determine that the external design needed to be re-designed but the strain gages were okay to use again."*

At the beginning of the semester, teams were only studying the end products of previous years' work, as opposed to the process undertaken. Examination of the earlier teams' website provided the current students with a better appreciation of the design tool's value. However, students were also prone to design fixation. This made it critical to provide them with not only the existing prototype but also with a multitude of other examples in order to spark their imaginations. Additionally, reading the rationale of previous teams enabled the current students to identify flaws in ideas and consequently improve their own justifications for design decisions.

3. *Organized Ideas*: *"It gave clear directions of [what] we needed to complete steps of the design process."*

For all of the student teams, design space exploration began with group brainstorming. While open discussion fosters strong ideation, making design decisions inherently involves the addition of structure. Using GloBDD helped students organize thoughts and categorize problem areas of the device and their process. Documenting every aspect of a design as complex as a medical device is a difficult task without a template or process to follow. Understanding how to explain processes and design specifics is an important skill to hone as an undergraduate. Further, GloBDD prevents students from skipping over entire design factors as the template includes a page dedicated to each factor. Since students are typically enrolled in four or five classes in addition to BioE 401, it was important to provide them with a means to organize all of the work that designing a biomedical device entails.

4. *Facilitated Design Process: "It helped to incorporate all of the design process. We were able to do quality research because we knew what we were looking for which helped when it came to designing and documenting the design decisions clearly on the website."*

In addition to helping clarify and organize ideas, students reported that the design tool helped keep them on task. They were able to identify which factors they had yet to take into consideration or work to improve, because the associated template pages were incomplete. The design tool not only offered examples of how to move about the design process, but it also provided a forum for students to document their own processes and decisions over the course of the semester. It further served to keep teams on track and remind them that they must constantly iterate and improve their design, as there were always more factors to consider.

Value of Documenting Design

Taken together, the assessment data provides several indications about the value of coherent and detailed documentation of design processes. In order to understand students' thoughts on documenting the design process, the authors asked each team in the end-of-class survey the following question: "What is the value of documenting the design process?" Table 4 provides a summary of the students' answers.

1. Documenting as a Method for Design Improvement (7/9 teams)
   We can see our design decisions from early in the project that we may have forgotten, and can go back or improve off those decisions
2. Compare/Validate Design Ideas (8/9 teams)
   It makes us think about what we are doing instead of making decisions without thinking them through clearly.
3. Tracks Design Progress (7/9 teams)
   It helps to document the progress in the design process so we can tell how much we have accomplished and what else needs to be done.
4. Future Teams/Professionals can understand why choices were made (8/9 teams)
   With everything documented, we could show it to the FDA or a commercial company.

Table 4. What is the Value of Documenting the Design Process?

The teams' answers showed they understood that documenting their process fostered a more sophisticated final product. Documentation provides a space to compare ideas and dissect reasoning in order to reach the best conclusion. Simultaneously, it requires engineers to write, which is something that does not occur in many courses. Since many professions necessitate technical writing, detailing design attributes is great practice for future careers.

GloBDD Strengths and Weaknesses

At the end of the semester, each student was asked to report the strengths and weaknesses of the design tool. The most highly cited aspects are listed below, in the words of the students themselves. The results shown in Table 5 were helpful in improving the tool and changing the design of the BioE 401 Course.

Strengths	Weaknesses
1. The tool let us see issues we would not have thought of	1. Some sections or questions do not apply to each specific device. Maybe consult specific design teams to develop project specific templates
2. The tool made us look into finding specific data on anthropometric measurements	2. Should have students start on the website much sooner because research is something that we could have started thinking about beforehand and it would have helped leave more time at the end of the semester to build the devices.
3. The tool made us look into the rationale for choosing the sensors and why we chose the sensor that we did	3. Some of the technical parts of the website were difficult for the entire team to understand without the background.
4. If we were unsure of something on the website, there were plenty of examples from the template as well as the past years designs so it made it easy to use. Also the Google site was a very easy way to make our website.	4. Add a timeline of design decisions that is only updated and not deleted.
5. The context section ensured that we did not only focus on the math, modeling, and engineering portion of this project, but rather kept the user in mind throughout the design process.	5. It was difficult to answer the Legal/Regulatory Section because we personally are not doing research and we don't have enough background to accurately answer the questions.

Table 5. Strengths and Weaknesses of the GloBDD Tool.

CONCLUSION

Biomedical devices used in the US and Europe are designed for sterile and controlled application scenarios with modern infrastructure and a well-educated workforce. When such devices designed for the Western world are used in developing countries, they fail to sustain because the designs do not meet local customer needs. In order to resolve these inadequacies and encourage the design of robust and rugged biomedical devices, educators created and validated the Global Biomedical Device Design tool. Assessment efforts indicate that by incorporating pertinent examples throughout the tool, GloBDD helped students determine factors that must be considered during the design process. The website template helped students make design decisions and provided a means of information organization, and a space for design decision documentation. Use of the tool ultimately enabled students to create better designs, faster. Fieldwork in Kenya validated that the student-made devices were culturally appropriate as well as physiologically sufficient.

From an instructor's point of view, the value of the tool lies in its ability to introduce students to the "unknown unknowns" — design constraints, systemic challenges and leverage points they previously would not have considered. This tool was transformative for the class itself and led to its reorganization. Though the class was previously structured to have three lectures every week, it has since changed to include a lab period that provides students time to work with both the tool and their teammates to improve their devices. Further, creation of the tool changed the course curriculum, as each design category and its corresponding examples served as a basis for class discussions. Though originally used for biomedical design, GloBDD is purposefully saved as website template, to facilitate the development of similar tools for other kinds of technologies. The tool has served as an inspiration for the design of an analogous design tool for exploring failure modes of agricultural technologies in the developing world and documenting design decisions made by student teams on such technologies.

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Peter Butler is a professor of Biomedical Engineering at Penn State University. Dr. Butler's principal research areas include mechanobiology of vascular cells and membranes, nanoparticle and nanoliposomal drug delivery, molecular spectroscopy using time-correlated, single-photon counting (TCSPC), molecular dynamics simulations, and design of medical devices for developing countries. TCSPC methods, in particular, will be useful for the proposed core because they can be used to determine particle size and encapsulation efficiency, and perform other important particle validation tasks. Dr. Butler has also directed the Biomaterials and Bionanotechnology Summer Institute, a training center for undergraduate research that has trained over 90 students in techniques in nanotechnology and biophotonics. He now teaches courses in molecular biophysics and quantitative microscopy and has written review articles and book chapters on mechanobiology, membrane mechanics, and edited a journal devoted to molecular imaging and mechanobiology.

APPENDIX: INSTRUCTOR GUIDELINES FOR GLOBAL BIOMEDICAL DEVICE DESIGN TOOL

Core Assumptions: GloBDD is intended to be open-ended. Instead of providing every consideration required for a design decision, it attempts to convey “unknown unknowns” - or aspects of design that students may not have thought to include.

GloBDD is a website template. Instructors can use the template as is, but also can edit the template for their own class. Possible edits include adding more examples, restructuring the design factors, or adding further meta-categories.

1. Students are randomly assigned into project teams.
2. Within each team, students pick an aspect of the product design they want to “champion.” The roles align with the category headings: System Integration, Context, Hardware, Software, Manufacturing, and Device Testing.
3. At the start of the semester, assign students teams to make their own website using GloBDD as a website template. For samples, see: http://www.globdd.com/Home/project-websites
4. GloBDD provides resources and examples by which students can grasp the concepts behind a design factor. Design factors can be assigned as homework or presented in the classroom. For example, a lecture can cover User Interface Design and User Experience Concerns. Alternatively, students can review the examples related to ‘Socio-economic factors’ and come to class prepared to discuss what socio-economic issues are most relevant for their own design. Throughout the semester, a course should cover all 19 design factors contained in GloBDD.
5. Cover the 19 design factors as they influence the students’ design process.

15-week Semester

- Socio-Cultural Factors
- Physiology & Clinical Indicator
- Signal Analysis
- Anthropometric Requirements

- Tech Interface
- User Interface
- COMSOL Modeling
- Price Point Analysis
- Ethical Considerations

- Physical Environment
- Form Factor
- Legal/ Regulatory
- Manufacturing
- Quality Control

- Materials
- Safety Issues
- User Experience
- Experimental Testing
- Calibration

6. As students move through the design process assign them to document design decisions made around each factor. This documentation ensures that teams have a well-informed rationale for each decision made. For example, under ‘Anthropometric Requirements’ a team designing an infant weighing scale can discuss the minimum size for the scale, as well as a reason for covering the scale in plastic (for ease of cleaning).