

## **Global Health Design: Clinical Immersion, Opportunity Identification and Definition, and Design Experiences**

### **Authors:**

Kathleen H. Sienko<sup>1,2</sup>, Maria R. Young<sup>1</sup>, Elsie Effah Kaufmann<sup>3</sup>, Samuel Obed<sup>4</sup>, Kwabena A. Danso<sup>5</sup>, Henry S. Opare-Addo<sup>5</sup>, Alex T. Odoi<sup>5</sup>, Cornelius A. Turpin<sup>5</sup>, Thomas O. Konney<sup>5</sup>, Zerihun Abebe<sup>6</sup>, Ibrahim Mohedas<sup>1</sup>, Aileen Huang-Saad<sup>2</sup>, Timothy R. B. Johnson<sup>7</sup>

<sup>1</sup> Department of Mechanical Engineering, University of Michigan, Ann Arbor, MI, USA

<sup>2</sup> Department of Biomedical Engineering, University of Michigan, Ann Arbor, MI, USA

<sup>3</sup> Department of Biomedical Engineering, University of Ghana, Accra, Ghana

<sup>4</sup> Department of Obstetrics and Gynecology, Korle Bu Teaching Hospital, Accra, Ghana

<sup>5</sup> Department of Obstetrics and Gynecology, Komfo Anokye Teaching Hospital, Kumasi, Ghana

<sup>6</sup> St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

<sup>7</sup> Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, MI, USA.

### **Abstract:**

We have developed an experiential learning global health design program that emphasizes direct interactions with stakeholders and firsthand exposure to the contexts in which solutions will be implemented. Students in the program gain practical hands-on experience identifying and defining unmet global health needs in low-resource settings, and apply human-centered and co-creative design approaches. Device designs that incorporate rigorously collected and analyzed first-hand data from diverse users and stakeholders rather than anecdotal or poorly represented information are more effective at meeting true needs. To date, more than 100 undergraduate student participants have identified hundreds of needs in collaboration with sub-Saharan and Asian healthcare providers. Approximately 400 students from the U.S., Ghana, Ethiopia, and Uganda have contributed to the generation of technology concept solutions to address these needs. Program outcomes include approximately 100 student design projects completed at multiple institutions, student-led design-based conference publications and journal articles, device commercialization, and peer-to-peer mentoring within traditional capstone design courses. In this paper we describe the curricular elements of the clinical immersion and design ethnography experience. Additionally, we describe programmatic best practices that have emerged over the past 10 years and challenges students encounter when performing this front-end design work.

**Keywords:** Global health, engineering design, needs finding, immersion, project-based learning, experiential learning

### 1. Introduction

Significant reports have called for transformations in engineering education that support additional types of learning beyond traditional disciplinary knowledge to prepare today's students for the rapidly changing world of technology development and the global economy [1-2]. While there is no question that students must be trained to be deep domain experts, it is no longer sufficient to only have deep disciplinary training. Specifically, students must be globally minded, socially responsible, adaptive learners, and capable of working across multiple disciplinary and cultural contexts [3].

In recognizing these needs, there has been a nationwide push for engineering reform, through the integration of experiential, authentic learning experiences [4]. In concert with the Accreditation Board for Engineering and Technology (ABET) accreditation requirements, most engineering programs have integrated design, primarily through senior capstone experiences, into their programs [5]. These design courses have largely become responsible for preparing students for engineering practice and they carry the responsibility for teaching engineering 2020 skills [5-6]. However, a recent study of how engineering undergraduate programs provide educational experiences to prepare the engineer of 2020 indicates, "when it comes to teaching design, practice lags pronouncement [6]." The

2014 Lattuca et al. nationwide study of engineering faculty, administrators, students and alumni found that while administrators reported that their “programs strongly emphasize design skills,” course-level faculty responses indicated that the topics were not as common as claimed. This discourse highlights the continued need for more effective, curricular frameworks for developing 21<sup>st</sup> century skills in engineering students.

Successful product design not only requires traditional design skills but also incorporation of the design context, including stakeholders’ behaviors and values [7, Ch. 32]. It can be difficult for stakeholders to articulate their needs and wants, particularly in terms of product attribute requirements and performance specifications, especially when working across cultures (professional, geographic, technical) [8-9]. For example, the design and development of health-related technologies for resource-limited settings requires a detailed consideration of the end user and target community that goes beyond traditional front-end engineering design processes. In a broader sense, social, cultural, and economic constraints must be considered for successful implementation of such technologies.

The purpose of this paper is to describe the evolution and implementation of a global health design program that provides students with practical hands-on experience identifying and defining engineering design problems through in-depth interactions with stakeholders from diverse cultural and disciplinary backgrounds at clinical field sites. Student participants apply human-centered and co-creative design approaches at clinical field sites (typically resource-constrained) to execute front-end design work and typically continue developing and assessing concept solutions within traditional capstone design courses. Student outcomes from this work demonstrate the value of experiential learning in preparing students to be engineers of 2020.

## 2. Background

As engineering education and practice increasingly recognize the benefits of early and accurate problem definition with respect to decreasing development costs and increasing the likelihood of adoption, there has been a shift to remove the proverbial “wall” that has historically separated engineering designers from direct interaction with stakeholders and contexts within which the solution will be implemented [10-15]. Furthermore, engineering designers are faced with many decisions during the front-end phases of design. A majority of these decisions are related to defining design problems and the associated requirements and specifications [10-13, 16]. Engineering designers need to participate not only in the planning phases associated with establishing the market need, but also during the physical collection of information that will inform the development of the design constraints and subsequent design decisions. In many traditional engineering design processes, engineering designers have been “walled off” from performing these functions directly, predominantly receiving information via one-way communication from marketing experts. This act of “throwing information over the wall” has precluded engineering designers from gaining an understanding of the broader context of design and has negatively affected design decisions by inadvertently promoting the use of anecdotal and poorly represented information, instead of rigorously-collected and analyzed first-hand data from diverse users and stakeholders [17]. These challenges are further compounded by the complexity of design problems facing society and the global nature of design teams; specifically, the emphasis on addressing technological challenges encountered in emerging market contexts (i.e., contexts that are not familiar to the engineering designers and that cannot be understood by design work performed exclusively within the research and development laboratory setting) and the trend toward multicultural and multidisciplinary design team members within multinational companies [18-20].

Design ethnography has evolved from ethnographic research methods developed by anthropologists to address the gap between designers and stakeholders. Applied during design processes, design ethnography allows one to gain a deep understanding of the stakeholders who will ultimately interact with a product and the environment where it will be used [21-23]. Design ethnography can be defined as “a portfolio of methods that have been developed to understand the perspectives of people by observing and participating in activities of everyday life [17]”. Design ethnography is increasingly being used within industrial and academic settings to capture broad societal, cultural, and personal behavioral patterns that are “important and relevant for the conception, design, and development of new products and services [17].” Several studies have attempted to identify the key characteristics or features of design ethnography [24]. For example, Arnould and Wallendorf describe the following characteristics of ethnography: 1) ethnography involves systematic data collection of customers in their natural setting, 2) ethnography involves extensive time spent by the researcher in the context of interest (this is key to bringing to light

the moments of ordinary life that can have significant effect on product design), 3) ethnography produces interpretations of events that those being studied would validate, and 4) ethnography involves synthesis of multiple data sources [24].

Extensive stakeholder engagement is critical to performing human-centered design [25-26]; common engagement methods include interviews, focus groups, surveys, observations, participatory design workshops, and co-creative partnerships [27]. Regardless of the methodology chosen, the objective is to acquire a thorough understanding of end-users and stakeholders to support informed design decisions. Interactions with end-users and other stakeholders have been shown to increase understanding of user needs, allow for the discovery of unanticipated needs and requirements, improve the final design and device interface, enhance aspects such as usability, quality, and functionality, limit self-reporting biases, and reduce development cost and time [17, 28-29].

The primary type of stakeholder engagement performed by students during design courses is design interviews. Interviewing stakeholders is a practice that spans the vast majority of human-centered design approaches including participatory design, ethnographic fieldwork, contextual design, lead user approach, among others [30]. Few support structures are available to novice designers when interviewing or preparing to interview stakeholders [31-32]. This leads to significant challenges when interviewing stakeholders including: ensuring that critical important topics are covered during an interview, asking appropriate questions, uncovering how people think or feel about certain topics, and obtaining information about broader social, political, or cultural factors that may affect the design [33-36]. Effective interviews with stakeholders tend to be semi-structured, thus requiring the interviewer to be flexible and opportunistic in order to elicit the “real” wants and needs [37-40]. Additionally, one must not only consider the challenge of conducting a stakeholder interview, but the challenge of gathering information from multiple stakeholders, synthesizing these data, and analyzing data in order to make informed design decisions.

Design decision making requires an iterative information gathering process [41]. While some information processing work can be defined as “information transfer,” where information is treated as an object and directly applied to the problem without further analysis or synthesis, “information use” requires that designers incorporate the information gathered into their existing knowledge and apply it to various design decisions, which is a more cognitively demanding task [42]. Studies have been conducted to understand how individuals identify information needs, seek out information, and apply information to problems [43]. Novices tend not to assess the quality and/or validity of the information obtained prior to applying it to their problem [44-47]. Similar results have been found for engineering students’ indiscriminate use of Internet sources [48]. Industry studies have shown that companies tend to rely on external information, use all information sources available, and devote significant time to gathering information during the problem solving process [49].

Developing a deep understanding of end-users and stakeholders requires designers to perform extensive information processing. Designers need both technical and non-technical skillsets to accomplish successful information processing [50-54]. Studies have demonstrated the differences between novices and experts in how they approach information gathering and the effect on design quality [55-58]. For example, a study of novices and experts performing a design task showed that novices spent less time gathering information and less time defining the scope of the design problem compared with experts [57]. Another study found that novice designers who spent more time defining their design problems produced higher quality designs [59]. In a prior study, most novice designers understood the value and benefit of information gathering and synthesis; however, they typically gathered less information and performed less synthesis than originally planned during design projects [60]. Moreover, although most novices acknowledged the benefits of incorporating stakeholders’ input into front-end design processes, they encountered obstacles and often interacted with stakeholders in a superficial manner [54, 61].

Available, accessible, and effective medical devices are critical for achieving the highest quality of care within health systems [62]. The availability and accessibility of medical devices in low-income countries (LICs) are typically affected by unreliable energy supply and water resources, limited infrastructure and distribution channels, inadequate or untrained workforces, lack of spare parts, required consumables, and high costs [63]. Roughly 80% of medical devices in LICs are acquired through donation [64]. Sales of older models of devices originally designed for use in high-income countries (HICs) and local production of medical devices that resemble technology designed for use in HICs are also common [64, 65, pp. 1841–1850]. However, medical devices designed for use in HICs are not

particularly effective in LICs; it has been shown that approximately 40% of medical devices designed for use in HICs are dysfunctional in LICs versus less than 1% in HICs [65, pp. 1841–1850, 66, pp. 507–535, 67]. Furthermore, the lack of available and accessible medical devices can sometimes create scenarios in which improvised and poorly assessed solutions are used or healthcare providers are required to rely too heavily on manual skills. There is a considerable gap between the benchtop-based design and development of safe and effective global health technologies and successful implementation, including attaining scale of technologies within a target setting [65-66]. Minimally, scaling is not achieved unless the technology addresses the unmet need. In many cases, needs are assumed and more frequently, not defined in a rigorous manner. Broader contextual factors associated with implementation are also essential to capture during the early stages of the design process rather than after the validation and production stages [68]. The most successful design approaches engage stakeholders to understand needs and consider cultural contexts as well as local and regional constraints [63, pp. 719–7225, 65, pp. 1841–1850].

### 3. Program Description

In 2007, the University of Michigan (UM) recognized that teaching the design process in the context of global health is an effective model for cultivating 21<sup>st</sup> century skills (e.g., design ethnography, stakeholder engagement, and information gathering, synthesis, and application) in today's engineering students. Global health is particularly attractive as a design context because it requires students to develop clinical literacy (e.g., obstetrics and gynecology) and cultural competency, and familiarize themselves with differences among health systems within a given setting as well as health challenges unique to specific communities. Students working within the global health design space also need to develop communication skills to effectively collaborate across disciplines. The World Health Organization states “in the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats [69].” Therefore, it is essential that students performing global health design work develop skills to interact and find common ground with those from various backgrounds.

Global health design programs are not unique to the UM. The oldest and most established program is Rice 360 Institute for Global Health [70]. Through undergraduate and graduate curricular and internship programs, Rice 360 focuses on the design, development, and implementation of low-cost, appropriate medical devices based on needs identified by healthcare partners in low-resource settings. In addition to Rice 360, there are several other U.S. universities with global health themed engineering design activities [71-72]. The breadth of activities within this space across domestic campuses demonstrates students' interests in applying their engineering skills to affect society. Students who participate in these programs report life changing experiences and lifelong learning outcomes, including a shift in career aspirations to focus on health related issues [73]. However, developing and executing such programs in an academic environment can be challenging. In this paper we describe our programs, challenges, and best practices.

#### 3.1 Motivations and History

The Global Health Design Initiative (GHDI) [74] was inspired by faculty leader Professor Kathleen Sienko's graduate training with the MIT-Harvard Division of Health Sciences and Technology. During the final year of her doctoral program, Sienko and a student colleague created a clinical immersion experience in India at the All India Institute of Medical Sciences and Rockland Hospital to seek first-hand knowledge about healthcare provision in an emerging market and health technology use within a resource-constrained clinical setting [75]. The lessons learned from Sienko's India-based clinical rotation informed the creation of a global health design experience for undergraduates, first piloted through the UM Global Intercultural Experience for Undergraduates (GIEU) program (<https://lsa.umich.edu/cgis/gieu.html>).

In alignment with the UM President's (Coleman) mission to extend existing collaborations with Ghanaian universities and forge new relationships in Ghana [76], Sienko developed a field site in the Department of Obstetrics and Gynecology at the Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana in collaboration with Prof./Dr. Kwabena Danso (Department Head) and with the assistance of Prof./Dr. Timothy Johnson and Prof./Dr. Frank Anderson from the UM Department of Obstetrics and Gynecology [77]. She led two groups of 11-13 diverse interdisciplinary undergraduate students to Ghana in May 2008 and July 2009 for 4-5 week immersive clinical

experiences in obstetrics and gynecology. Students stayed with local families and spent their work weeks attending departmental clinical morning meetings, observing and interviewing clinicians and nurses in seven units including labor and delivery, elective and emergency surgery, antenatal care, mother/baby care, family planning clinic, outpatient department, and gynecological complications, and traveling in pairs to a rural district hospital to observe practices in secondary and primary healthcare setting. The teams identified several needs that were both of importance to collaborators at KATH and deemed suitable for pursuit in a senior design course.

In 2010, following two years of developing partnerships in Ghana through the GIEU program, Sienko led a UM College of Engineering supported clinical immersion experience for a group of 13 students comprising 10 engineering students and three non-engineering students (the first “Design for Global Health” cohort). Unlike the GIEU participants, these students committed to one or more subsequent semesters of capstone design work to address needs identified through their project scoping activities in Ghana. Since 2010, the clinical immersion experience and the supporting preparatory and follow-on design course offerings have evolved considerably to improve student performance at the field sites and support concept solution development following the completion of the field site experience.

### 3.2 Model/Approach

Our experiential-learning global health design offerings emphasize the use of design ethnography, direct interactions with stakeholders, and firsthand exposure to the contexts in which solutions will be implemented. Students in the program gain practical hands-on experience identifying and defining unmet health needs in resource-constrained settings, and apply human- and user-centered and co-creative design approaches to address these needs. The core elements common across all of our programmatic and curricular offerings are pre-immersion training, clinical immersion, and front-end design work (Figure 1). Prior to clinical immersion, students study front-end design processes and learn about a specific clinical discipline. Students then gain practical hands-on experience identifying and defining engineering design problems through in-depth interactions with stakeholders from diverse cultural and disciplinary backgrounds at clinical field sites. During both the clinical immersion experience and capstone engineering design course work, students practice applying human-centered and co-creative design approaches to address essential healthcare challenges.

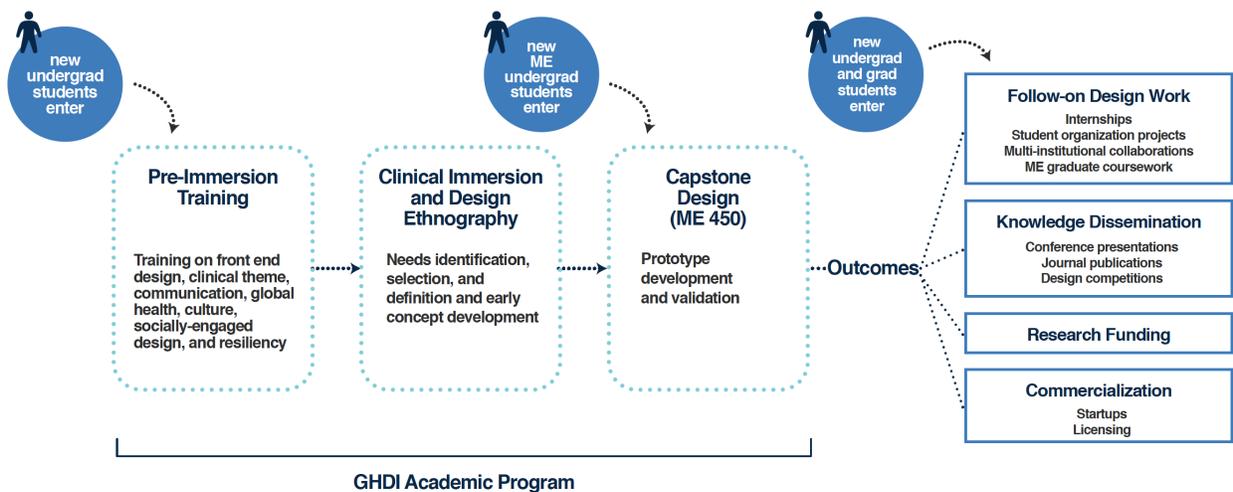


Figure 1. Global health design academic program components illustrating typical student entry points and potential outcomes. Engineering and non-engineering students may enter the program prior to the pre-immersion training component or participate in follow-on design work; however, mechanical engineering (ME) students not affiliated with the program may pursue their capstone design (ME 450) project based on a need identified by program students during a clinical immersion experience.

### 3.3 Pre-immersion Training

In preparation for the clinical immersion and design ethnography experience, students complete front-end design coursework (in a formal classroom setting or via an asynchronous online learning platform) focused on design ethnography techniques as well as thematic clinical readings and written assignments (e.g., obstetrics and gynecology) to develop clinical literacy. Additionally, students study communication (e.g., formulation and delivery of mission statements, management of expectations, communication of technical content to culturally and professionally diverse stakeholder groups), global health (e.g., international aid/global health trends, strategies, and perspectives, global health technologies), culture (e.g., country/community specific language and customs, clinical etiquette), socially-engaged design (e.g., entering, engaging with, and exiting communities, self/social identities), and resiliency topics through readings, discussions, and hands-on skills training sessions with members of the extended instructional team.

### 3.4 Pre-immersion Training Evolution

Initially, the pre-immersion training was offered through a credit-bearing independent study course. This voluntarily-taught (i.e., did not count toward departmental teaching obligations) “one-room schoolhouse” style course was challenging, as it required a single faculty member to cover topics spanning several disciplines as well as life skills. Course topics included problem identification [78, Ch. 1.2] and need statement development and prioritization [78, Ch. 1.3]; product requirements and engineering specifications; cultural awareness; maternal health; obstetrics and gynecology [79]; patient interaction (e.g., Health Insurance Portability and Accountability Act (HIPAA)), history and physical exam skills; and health, safety and security. Students were also required (and continue to be required) to perform clinical observations at UM to ensure that they have some experience within a clinical setting prior to the formal clinical immersion experience. In 2011, several multi-disciplinary faculty (mechanical, biomedical, entrepreneurship and design science) co-developed and co-taught a design primer class titled Introduction to the Design Process, given the increasing recognition of the importance of exposing engineering students to opportunity/problem identification before detailed, technical engineering design. The introduction of the design primer course facilitated a transition to a more desirable “two-room schoolhouse” model that decoupled front-end design topics from the clinical observations, global health, and life skill topics, and reduced the teaching load on the single faculty leader. The design primer course was eventually revamped and subsequently offered as a standalone three credit Front-End Design course that covers opportunity discovery, problem definition, mechanisms for gathering data from users and other stakeholders, translation of user data into design requirements, creation of innovative solutions during concept generation, representation of design ideas, and evaluation of possible solutions.

In 2015, an asynchronous learning platform called the Socially Engaged Design Academy (SEDA) was developed by the UM Center for Socially Engaged Design (<http://csed.engin.umich.edu/>), in part to provide resources to support faculties’ curricular and co-curricular educational needs [80-81]. The introduction of learning blocks on needs assessments, observations, interviews, and design ethnography allowed for the completion of front-end design training outside of the classroom environment, and learning blocks on health, safety and security enabled life skill topics to be offered to students by non-engineering faculty. The present model still requires students to participate in a credit-bearing independent study course to cover the global health, cultural, and clinically-relevant topics.

Our pre-immersion training model has been adapted for use within other settings (e.g., China, Ethiopia, Kenya), for other global health/clinical topics (e.g., surgery, physical medicine and rehabilitation, water access, traffic safety), and by students at collaborating institutions (e.g., University of Ghana (UG), Biomedical Engineering Department). For example, biomedical engineering (BME) students at the UG complete the same obstetrics and gynecology readings and assignments and select front-end design readings and assignments (assignments submitted to and graded by UM instructional aides) prior to pairing up with UM students working at the Korle Bu Teaching Hospital (KBTH) field site (Accra, Ghana). UG BME students also complete two design courses at their institution that cover the engineering design process and emphasize materials for biomedical applications.

### 3.5 Clinical Immersion & Design Ethnography Experience

During the two-month clinical immersion and design ethnography experience, student teams consisting of UM

engineering and non-engineering students (and sometimes institutions affiliated with the clinical field sites, e.g., UG), are tasked with identifying and prioritizing unmet needs, selecting a need to pursue during a follow-on capstone design course at their respective institutions, and defining the need through the development of product requirements and engineering specifications. Needs are typically identified through a combination of clinical observations, interviews, focus groups, and surveys, and prioritized with the use of custom prioritization rubrics developed by the students in collaboration with engineering, clinical, and professional/industry mentors. Product requirements and engineering specifications are developed through a combination of direct interaction with stakeholders as well as through benchmarking, literature review, and early-stage prototyping. As part of the field site work, students are also asked to conduct and document a context assessment. Throughout the pre-immersion and immersion work students follow a structured design activity plan and receive guidance in the form of frequent instructional meetings and design work critiques (e.g., three telecons per week, three written design work deliverables per week).

### 3.6 Clinical Immersion & Design Ethnography Experience Evolution

The structure of the immersion experience has become more formalized over the past several years. Student teams are typically challenged with generating at least 100 need statements during their 6-8 week immersion experience and performing a context assessment. Drafts of the need statements are uploaded to a project website 2-3 times a week and written and verbal feedback regarding the quality of the need statements are provided remotely three and two times a week, respectively. Student teams are also tasked with developing a rubric to prioritize their need statements and obtaining input from field site stakeholders on their highest ranking need statements. During the last several weeks of the immersion experience, students shift their attention from general to focused observations and interviews (“deep dive”) for the purpose of obtaining data to inform their product requirements and engineering specifications.

During the first three years of the program, the clinical immersion component was 4-6 weeks. During the summer of 2011, the clinical immersion component was extended to eight weeks to provide students with adequate time to acclimate to their new environments (context) and extend the design work performed at the field site. Originally, students defined needs and developed product requirements and engineering specifications during the 4-6 week immersion experience. The eight week time period also allowed students to develop and use low-fidelity prototypes for problem-solution co-evolution, and obtain feedback from stakeholders on early-stage concept solutions.

Also in 2011, with industry support, modifications to the model were made to accommodate minimally invasive surgery as a clinical theme and multiple clinical immersion field sites were piloted in China with a group of UM undergraduate engineering and business students. In 2011, Sienko also piloted the first multinational student needs finding team in collaboration with Dr. Elsie Effah Kaufmann from the UG and Prof./Dr. Samuel Obed from the KBTH in Accra, Ghana [82]. Cancer and cardiovascular surgical themes were implemented in China with support from two industry partners, and an academic based collaboration with St. Paul’s Hospital Millennium Medical College in Addis Ababa, Ethiopia was established in 2013.

UG students in the BME program are required to complete a 6-8 week internship in a clinical, research or industrial setting to gain practical experience and identify needs, which they can address during their senior capstone design project. Typically, 3-4 UG students per year are placed with UM students at the KBTH to satisfy this program requirement. UG participants are selected on the basis of their academic background as well as their capstone design project interests. Selected students also indicate a willingness to complete the additional pre-clinical immersion training.

### 3.7. Capstone Design

Currently, UM students participating in the needs finding and defining activities at field sites are required to enroll in a capstone design course. In the earliest offerings of the clinical immersion and design ethnography experience (e.g., GIEU), this was not a requirement (i.e., identified and defined needs were included in the capstone design course and addressed by other students). The majority of participants enroll in the Department of Mechanical Engineering’s Capstone Design and Manufacturing Course (single semester), which aims to expose students to the

design process from concept development through analysis to prototype validation and report. Five faculty members typically co-teach the course each semester and supervise approximately six four-person teams per semester. This course has also accommodated small numbers of non-mechanical engineering students and non-engineering students since 2010. Sienko has regularly taught this class during the fall semester, enabling her to directly supervise the global health design projects in her section. UG participants enroll in a multi-semester design project course with similar aims at the UG and typically work in teams of up to five students. The UM and UG partners intentionally decided to coordinate pre-immersion training and the clinical immersion and design ethnography experience, but not the capstone design courses due to differences in course timelines, structures, and resources. However, past participants and other affiliates from UM have visited the UG design project class to exchange information about their respective experiences and to demonstrate outcomes from their single semester design courses, including prototypes. The visits have facilitated recruitment of future UG cohorts and have created an opportunity for the senior capstone design students from both universities to meet following the completion of the clinical immersion and design ethnography experience, strengthened collaboration between the two institutions more generally, and encouraged new partnerships among faculty.

### 3.8. Follow-on Design Course Opportunities

Following the completion of the Department of Mechanical Engineering Capstone Design and Manufacturing course, UM students have the option of pursuing their project through follow-on design courses (e.g., independent study or graduate level medical device usability testing and iterative design). The independent study course is project-based and requires students to meet regularly with a faculty instructor and perform additional usability and validation testing to inform iterative design. Students often return to their clinical field site for one week during their mid-semester break with prototypes to gain direct feedback from stakeholders. Periodically, students simultaneously participate in non-engineering courses that further the development of their project (e.g., UM Center for Entrepreneurship Social Venture Creation course). Some participants opt to continue their projects through co-curricular student groups (e.g., M-HEAL, an engineering student group focused on developing healthcare solutions for low-resource international communities [83-84]).

### 3.9. Academic Offerings

UM GHDI participants are eligible to earn credit for the front-end design coursework (3 credits), pre-immersion training (up to 2 credits), design ethnography and clinical immersion experience (up to 3 credits), capstone engineering design course (4 credits), and follow-on design courses (typically 3 credits). Students who complete the traditional “academic program” sequence including the follow-on design course also fulfill the majority of the requirements for the UM College of Engineering Multidisciplinary Design Program (MDP) Minor: Specialization in Global Health Design. Students who are interested in earning a global health design distinction on their transcript, but are unable to complete the time intensive coursework demanded by the MDP Minor Specialization, can complete a “mini-minor” in global health design (officially termed Specialized Study Program in Global Health Design (PGHD)). PGHD requires 9 credits of coursework and does not include a fieldwork component. In 2015, Sienko piloted a global health paid summer design internship program to enable students with academic coursework constraints to gain critical design skills (e.g., opportunity identification and definition). The internship has increased the participation of non-engineering students and has afforded students the ability to obtain a short-term work experience in the global health space without financial cost to participate, as is common in many programs offered by non-governmental organizations and other academic institutions. Additionally, it has provided a mechanism for further developing promising concept solutions.

## 4. Outcomes

### 4.1. Intended educational outcomes

Intended educational outcomes include exposure to and experiential training with: identifying and defining engineering design opportunities through clinical immersion; applying co-creative user- and context-centered design processes; gathering, synthesizing, and using information to inform design decisions; considering the cultural

influences on an engineering problem and the implications of technology introduction to a community; considering a wide range of unique constraints; developing interdisciplinary and intercultural communication skills; and understanding the local and broader contexts of design. Program outcomes over the last 10 years include the identification of more than 700 unique unmet global health needs, completion of approximately 100 student design projects at multiple institutions, publication of student-led design-based conference and journal articles, technology transfer, and peer-to-peer mentoring within traditional capstone design courses (i.e., clinical immersion and design ethnography experience students partner with traditional capstone design students and provide insight into the broader contextual issues of the design problems).

#### 4.2. Participants

Approximately 400 undergraduate and graduate students have contributed to the design of global health technologies through the Global Health Design Initiative, with over 100 students participating in clinical immersion experiences. Students are either accepted to the ‘Design for Global Health Academic Program’, accepted to the ‘Design for Global Health Internship’, or enroll in a project-based course focused on a need identified by a GHDI student participant. These courses include capstone senior mechanical engineering design, upper level courses in the School of Art and Design, and graduate level courses in mechanical engineering. Additional opportunities for graduate students exist for 1-8 week clinical immersion experiences.

Applications for the short-term paid internship significantly outnumber those for the traditional credit-bearing academic program described above (e.g., 50-150 vs. 5-20 student applicants per year). This is due to the extensive academic and fieldwork commitments of the academic program and the application constraints. The academic program’s admissions requirements limit the application pool to rising seniors, while the internship is open to sophomore level or higher undergraduate and graduate level students.

To date, we have seen a balance of female and male participants (Table 1), potentially due to the recognized trend that women in engineering find their work more meaningful when combined with another discipline (i.e., social justice, global health, international studies) [85-86].

Table 1. Illustrative sample of undergraduate participants from a subset of GHDI offerings (academic program and internship) by gender and major from 2010-2017

	Gender		Major			
	Male	Female	Mech. Eng.	Biomed. Eng.	Other Eng.	Non-Eng.
UM Students	32	40	20	24	4	24
UG Students	12	2	0	14	0	0

#### 4.3. Opportunity Discovery

Participants have completed clinical needs finding experiences at multiple teaching hospitals in Ghana, Ethiopia, China, Kenya, and Nicaragua (Table 2). Clinical themes include obstetric and gynecology, surgery, traffic safety, water access, and physical medicine and rehabilitation. Needs vary in terms of specificity and focus; therefore, it is possible for one designed technology to address several of the unique needs identified and for more than one need to be combined to describe a comprehensive essential healthcare challenge.

Table 2. Summary of clinical needs finding outcomes in Ghana, Ethiopia, Kenya, and China for a subset of clinical themes

Clinical Theme	Field site location	Total # unique needs identified	# Needs assessments performed for clinical theme to date	Average # needs identified per needs assessment
Obstetrics and Gynecology	Kumasi, Accra, and Navrongo, Ghana	886	13	90
	Addis Ababa, Ethiopia		1	98
Surgery	Multiple cities, China	305	3	104
Traffic Safety	Addis Ababa, Ethiopia	104	1	104
Water Access	Meru, Kenya	105	1	105
Physical Medicine and Rehabilitation	Meru, Kenya	120	1	120

#### 4.4. Projects and case examples

GHDI has supported UM students through the design of approximately 100 global health technologies. Project themes include obstetrics and gynecology, infant health, surgery, physical medicine and rehabilitation, and others including medical equipment, home use medical devices, water access and traffic safety. The vast majority of these projects have been supported through academic coursework, with the remainder supported through the internship program. UG has completed approximately ten obstetrics and gynecology themed projects since 2011.

##### Case 1: Portable Obstetrics & Gynecology Examination Equipment

In the rural Sene District in the Brong-Ahafo Region in Ghana, pregnant women often travel tens of miles on foot to be seen by a nurse, midwife, or clinician at the District or Regional Hospital. Presently, a cadre of community health care workers are being trained to provide health care services in rural communities and at Community Health and Planning Services (CHPS) compounds to address non-emergency obstetrics and gynecology issues. The goal of this project was to design and build a low-cost portable pelvis examination table for use by CHPS health care workers. This need was first identified by a GIEU student during the summer of 2008. Following his initial trip to Ghana, he and three other mechanical engineering students (non-GIEU participants) designed a portable gynecological examination table for use by CHPS workers for their capstone design course project. The former GIEU participant returned to Ghana to obtain feedback on his team’s design from clinicians, nurses, midwives, community health care workers, and pregnant women and subsequently completed a second semester independent design course focusing on improving the portable examination table [87]. Project findings were disseminated to a co-curricular design team within the M-HEAL organization that was concurrently pursuing a similar need in Nicaragua. M-HEAL students have manufactured several prototype iterations over the past eight years and performed pre-clinical testing.

##### Case 2: Automated Blood Transfusion Device

Obstetric hemorrhage is the leading cause of maternal mortality in West Africa, with over a quarter of these deaths attributed to a lack of available and accessible donated blood [88]. During the summer of 2010, students in the Design for Global Health Academic Program identified the need for a simple, low-cost, purely mechanical device to salvage blood during obstetric hemorrhage, specifically during ruptured ectopic pregnancies. Students developed early iterations of their concept solution during their capstone design course at UM and obtained feedback about their design in Ghana during March 2011 as part of their follow-on design course. The concept solution resembles

an oversized syringe, and utilizes a series of one-way valves to salvage blood from a body cavity and filter the blood into a blood bag for immediate transfusion back into the patient (Figure 2) [89]. The student team presented their work at the 2011 American Society of Mechanical Engineers Design of Medical Devices Conference. Several students enrolled in the UM Social Venture Creation course and formed the startup company Design Innovations for Infants and Mothers Everywhere (DIIME). Following graduation, one of the co-founders of DIIME co-founded the for-profit company Sisu Global Health (<http://www.sisuglobalhealth.com/>) and continued to develop the technology of the blood salvage device. Now patented and titled, “Hemafuse,” Sisu is completing clinical trials in Ethiopia with a planned roll out of the device in the Ghanaian market in 2018.

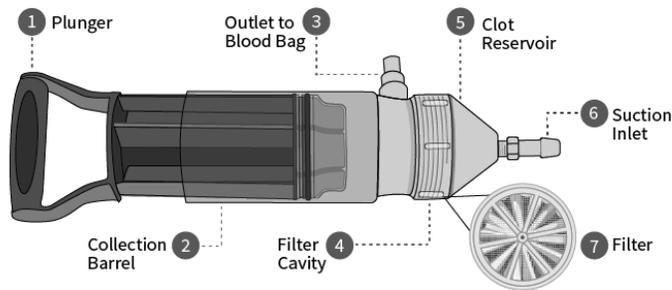


Figure 2: Hemafuse, blood salvage device [90]. Photo courtesy of Sisu Global Health.

### Case 3: Cervical Cancer Screening Simulator

Cervical cancer causes the death of nearly 200,000 women each year in lower-middle income countries [91]. Visual inspection of the cervix with acetic acid (VIA) is an effective low-cost method to screen for cervical cancer but is not used widely, due to a lack of training and awareness of the method. Two students identified the need for a training model to support VIA training for midwives and midwifery students in Ghana in 2013 as participants in the Design for Global Health Academic Program. With input from project stakeholders and the instructional team, the students specifically chose to work on a simulator-based design to increase the likelihood of accelerated usability testing and implementation due to a decreased amount of regulatory hurdles. The student team designed and manufactured a physical trainer in their UM capstone mechanical engineering design course and returned to Ghana in the following months as part of a second semester independent design course to receive feedback on the initial prototype. The trainer is a low-cost model built to aid midwives in learning to perform VIA using realistic simulation with an electronic feedback mechanism (Figure 3). The training model allows students to practice VIA at their own pace with exposure to many different VIA outcomes, enabling them to gain confidence in performing VIA before screening patients [92].



Figure 3: Early-stage prototype of the Visualize trainer. The box-trainer (shown) allows students and midwives to practice inserting a speculum and swabbing the cervix, inspect several custom dual image tabs (shown), and diagnose and receive feedback through a built-in LCD screen.

Since graduation, the students have continued to work on the simulator device design ([www.visualizecc.org](http://www.visualizecc.org)) and returned to Ghana several times to co-iterate with stakeholders and pilot devices at local midwifery schools and with independent midwife trainees. The project continues with the support of undergraduate and graduate student contributions at multiple U.S. universities.

#### Case 4: Assistive device for implantable contraceptives

During the summer of 2013, two UM doctoral candidates (mechanical engineering and design science) spent four weeks conducting a needs assessment in the Obstetrics and Gynecology Department of St. Paul's Millennium Teaching Hospital in Addis Ababa, Ethiopia. These graduate students identified the need for a device to assist in the insertion of subcutaneous long-action contraceptives. This need was seeded as a capstone design course project and mentored by one of the graduate students who initially identified the need [93]. The graduate student continued to work on the concept as part of his dissertation research and the project, now named SubQ Assist (Figure 4), has obtained financial support from multiple funding agencies including Saving Lives at Birth. Pre-clinical testing and usability studies have been conducted in the U.S. and Ethiopia and clinical trials are pending.



Figure 4: The SubQ Assist device (prototype shown) is placed beneath a blood pressure cuff to assist in the insertion of subcutaneous polymer rod implant contraceptives.

#### Case 5: Blood Warming Device

During a multinational team needs finding experience in 2012, two students from the UG selected the need for a blood warming device to pursue in their UG biomedical engineering capstone design course. In the absence of a blood warming device, patients are at risk of receiving transfusions of blood at cold temperatures and thereby developing hypothermia, which can be fatal [94]. The UG student team designed, manufactured, and tested a low-cost blood warming device using electrical current, thermal regulation and distribution systems, and a heat retaining polymer foam housing [95]. This project inspired an additional undergraduate design project (co-supervised by Dr. Effah Kaufmann) in the Department of Computer Engineering at UG.

#### 4.5. Engineering Education Research Findings

UM capstone design instructors' positive interactions with former student participants in the front-end design activities associated with the clinical immersion and design ethnography experience motivated the attempt to better understand how the experience affected students' abilities to execute front-end design work. Specifically, instructors anecdotally noted that past participants engaged more frequently with stakeholders throughout the capstone design course, used a larger and broader set of information sources to develop product requirements and engineering specifications, and considered local material and manufacturing options. Additionally, UG faculty and instructors noted higher academic performance in their capstone design course setting and an increased level of confidence among former UG student participants because they are typically ahead of their non-immersion peers with respect to opportunity discovery and an overall understanding of the engineering design process. We initially attempted to use pre-/post- clinical immersion and design ethnography experience surveys (e.g., Likert) to assess the effects of the experience on the students' self-perceptions of their design proficiencies and abilities to work on a team, and to capture their general attitudes towards the engineering design process. The failure of the survey to reflect the instructors' narratives as well as differentiate between participants and non-participants prompted partnership with an engineering education research expert to investigate the major challenges associated with executing the unstructured nature of front-end design (supported through a NSF RIGEE/RIEF grant). As we progressed, we noted significant gaps within the literature with respect to how students more generally performed front-end design work and engaged with stakeholders to make design decisions. Over the course of several studies, we have sought to better understand 1) how clinical immersion and needs identification and definition experiences impact student learning and design work and 2) more generally, how design students engage with stakeholders during front-end design activities. Below we summarize the major findings from several research studies.

Within our studies we have specifically investigated how student designers approach front-end design phases and how they engage with stakeholders to make design decisions. During front-end design, we have found that student

teams plan to use a diverse set of information sources (including significant interaction with stakeholders), however, when actually executing these phases, teams tend to focus on a much smaller (less diverse) set of information sources and dramatically lower their use of stakeholder interactions [60]. We have also observed that design teams struggle when attempting to synthesize and analyze information gathered using design ethnography methods [61]. The challenge increases when students engage with multiple stakeholders with differing opinions regarding the development of a product [61, 96].

We also observed that most design teams engaged with stakeholders during the front-end design phases, but their engagement decreased as the semester progressed [54]. During interactions with stakeholders, we observed specific factors that increased the perceived utility of these interactions in supporting design decisions. For example, design teams who engaged with stakeholders after they defined clear and explicit goals tended to find interactions with stakeholders to be more useful [96]. Design teams were also more likely to find an interaction useful when they engaged with a subject matter expert (as opposed to an end-user or other stakeholder) [96].

The clinical immersion and design ethnography experience (referred to as “immersion” below) has had a discernable effect on how students view front-end design work, approach information processing for design applications, and engage with stakeholders throughout the design process. Students who have completed the clinical immersion and design ethnography experience have displayed more advanced design practices with respect to requirements elicitation and development and problem definition. For example, within an experimentally controlled front-end design task study, immersion students developed the highest quality product requirements (when compared to non-immersion students) [97]. Immersion students displayed more iterative design behavior, narrowed the focus of their design efforts to reduce the ambiguity of the design problem, and displayed advanced stakeholder engagement techniques (using focus groups and validating conclusions drawn from interviews through follow-up sessions) [97].

Immersion students also tended to use more advanced information processing techniques within their design work. Our studies have shown that immersion students consult a broader range of information sources than non-immersion students, and are less likely to be dependent on a small number of information sources during the design process [97]. Immersion students are also more engaged with stakeholders throughout the design process; they begin with a more human-centered view of the design process and continue to engage with stakeholders throughout the semester, whereas other design teams slowly reduce their stakeholder engagement as the semester continues [96, 98].

## 5. Discussion

### 5.1. Best practices/Lessons learned

Over the past 10 years we have made numerous changes to our programs to improve student performance and experiences as well as increase the likelihood of pursuing needs that could potentially translate into clinical practice.

#### Real-/semi(real)- time feedback/”Closing the loop”

One of the most important instructional approaches that has impacted the quality of the field-based student work is the inclusion of mechanisms to provide real-time and/or semi- real-time feedback to the participants. The original 2008 and 2009 GIEU student cohorts were accompanied by a faculty mentor and student assistant (programmatic requirement) for the entirety of the 4-5 week experience. Given the long-term unfeasibility of sustained faculty support at the field site, we shifted to a version that included a short-term faculty and/or instructional aide visit to the field site supplemented by a minimum of two ~30 min phone calls per week to discuss technical challenges. Faculty and instructional aides typically model observation, interviewing, and reflective practice behaviors while at the field site and students are provided with feedback immediately after they perform design ethnography techniques. In particular, impromptu and short (e.g., 3-5 min) “hallway” style interviews are demonstrated and practiced with instructional support. To facilitate feedback at a distance, students are required to submit drafts of project-related deliverables (e.g., need statements, prioritization rubrics, product requirements and engineering specifications) three days per week. We have found that it is important to provide structured deliverables and regular deadlines for the design ethnography and needs finding work since it is inherently open-ended and time at the field site can otherwise be mismanaged. As the number of field sites and participants has increased, we have increased our dependence on hourly-wage instructional aides. Typically, these are past participants or current graduate students with relevant

experience that commit to working five to ten hrs/week to provide written feedback for the submitted deliverables during the field site activities. We have also begun to leverage past participants or part-time staff to accompany the students to the field site. If travel support for faculty and/or instructional staff (including past participants) is available, we have found it to be most beneficial to accompany the student participants during their first week and approximately during their fourth or fifth week when students are finalizing the selection of needs to pursue and beginning their “deep dives”.

### Partnerships

The programs described herein would not have been possible without partnerships. We have primarily leveraged three types of partners: 1) teaching hospitals affiliated with universities with engineering schools in low- and middle-income countries, 2) UM departments, programs, and units, and 3) clinical faculty at UM. Selection of the first field site was largely determined by considering UM’s strategic plan as well as national languages and overall political stability. Ghana, and specifically KATH and KBTH were initially singled out as potential teaching hospital partners due to the long-standing history (approximately 25 years at that time) with the UM Department of Obstetrics and Gynecology [77, 99,100]. Teaching hospitals share a common education mission and are equipped to support students. It is critical to have support from the leadership at both the home and partnering institution, e.g., head of department, especially given the unique nature of having engineering students in a clinical environment. Although engineering students’ presence in clinical settings is increasingly common in U.S.-based healthcare facilities, it is still a relatively unusual practice in sub-Saharan Africa and China. In many cases, it has taken three to five years to overcome the initial hesitations by international healthcare providers to engage with engineering students, despite the support of their leadership. As previously mentioned, GIEU provided a vehicle for establishing a partnership with KATH and provided programmatic support including program marketing to students, management of applications and interview scheduling, and pre-departure training related to travel safety. For follow-on cohorts, we leveraged additional resources at UM for various aspects of the programs, including the African Studies Center, International Institute, International Programs in Engineering, Center for Entrepreneurship, and Counseling and Psychological Services. Furthermore, it has been beneficial for the UM students to identify one or more UM clinical faculty as mentors and if possible, consider their recommendations during the needs selection process since they frequently become the main source of clinical feedback during the academic semester; single semester capstone design courses require design decisions to be made at a pace that does not typically accommodate regular feedback from our international partners. We have also leveraged our ties with UM clinical departments to provide students with opportunities to meet with visiting residents and scholars from sub-Saharan Africa during the academic year.

### Needs to pursue

Selection of one or more needs to pursue can be a difficult and time intensive activity. Student participants frequently experience difficulty during this portion of the work and often search for the “best” need to pursue. Our prioritization rubrics have generally included input from key stakeholders (e.g., LIC department head) and have taken into consideration the appropriateness of the topic with respect to fit for inclusion in a capstone design course as well as the students’ interests, among other traditional considerations [101]. Over time we have intentionally diversified our portfolio of selected needs to include a limited number of simulator/trainer, equipment, and process/operations projects. These types of projects have the potential to be transferred to our partners for implementation on a much shorter timescale than medical devices. However, we have remained committed to pursuing the design of medical devices, despite the numerous challenges associated with bringing a medical device to market [66, 102]. At UM, we have had limited success with completing electromechanical projects within a single semester mechanical engineering design course and have generally found these types of projects to be better suited to teams comprising students with electrical engineering experience, multi-semester design projects, and/or projects that continue over multiple years. UG instructional faculty have also noted that some of the capstone projects undertaken have been overly ambitious, leading to situations where the projects could not be adequately completed in the time available. It is common practice to provide our cohorts with access to prior cohorts’ need statements and prioritization rubrics. After several years of performing needs assessments in a single location, we began to observe saturation in needs; therefore, to provide new cohorts with opportunities to practice needs findings while leveraging the prior work, we included general needs finding activities within the first 2-4 weeks to supplement the existing

lists of needs while students perform “deep dives” on a select number of previously identified high priority needs.

#### Peer-to-peer learning and student interactions

Given that it is not practical for all students to participate in the type of clinical immersion and design ethnography experience described above, UM and UG have intentionally paired participants with non-participants within capstone design teams. The team-/project-based nature of the courses encourages the transfer of knowledge and experience with cultural and contextual constraints among teammates. For example, students who have not participated in a clinical immersion experience often ask deep and insightful questions about their peers’ experiences in an attempt to better understand the broader context of the design project, thereby providing the clinical immersion students with additional opportunities for meaningful reflection. The non-participants also benefit from the opportunity to work closely with peers who can serve as consultants and proxy end users/stakeholders for their projects. Additionally, UG student participants in the immersion experience have expressed feeling less anxious about their required internship because they are assured of identifying multiple needs for consideration in their capstone design project. They also appreciate the opportunity to interact with students from a U.S. institution and work within an international team setting, since the UG rarely has non-African students enrolled.

#### 5.2. Challenges

The major challenges that we have encountered and continue to address are not unexpected. Funding has been an issue since the beginning of our work, but the funding needs have shifted from student travel costs to programmatic support. In recent years we shifted to a fully-funded student participation model, given that funding was frequently a barrier to participation. The majority of the current support is a result of gifts from donors (UM also provides partial funding that is supplemented by internal and external grants). GHDI typically provides small stipends for local transportation and materials and supplies to UG participants. Presently, the greatest direct funding challenge is coupled to the scaling challenge. As we offer increased opportunities at various field sites (including domestic field sites), we struggle to cover administrative and instructional needs-related costs, including programmatic marketing; student recruitment, selection, and training; field site support; and faculty effort and instructional aides wages, etc. Collaborations with multinational medical device companies have expanded field site offerings in China and provided student participants with both salary and travel stipends.

Although our primary driver is education, all stakeholders involved in these projects have the ultimate goal of implementing successful concept solutions with the hope of improving healthcare provision for vulnerable communities. Beyond diversifying selected needs, we seek to increase the likelihood of implementing sustainable program-generated technologies. Typical pathways for potentially promising concept solutions include multiple semesters within a design course to refine the concept, faculty- and/or student-led grant proposal or business competition submissions, and grant-funded graduate student design work. Given the short life-cycle of engineering undergraduates, continuity is reliant on the involvement of a graduate student or faculty member committed to the long-term management of the project. This limitation reduces the ability to leverage the benefits of scale with multiple undergraduate teams pursuing diversified needs. Development is also delayed as a result of the need to re-educate each incoming team on previous work, findings and challenges.

Intellectual property practices and strategies for protecting inventions remain as challenges. Our current approach is to disclose the invention to our technology transfer office (at UM, undergraduate students own their own IP) and ask students to sign a non-exclusive license agreement to UM so that continued effort can occur on the project once students graduate.

At UG, prototyping has posed challenges to students due to unavailable or unaffordable processing facilities and materials. More significantly, none of the projects have gone beyond the prototyping stage to actual commercialization or delivery to the end users, mostly because there are no identifiable industries dedicated to research, development and manufacturing of biomedical devices in Ghana and the Department of Biomedical Engineering has not had the necessary resources to support such efforts.

From an engineering education perspective, we have struggled with how best to quantify outcomes. This struggle has in part influenced the engineering education research interests of several faculty members and has motivated

numerous grant proposals and engineering education research papers. Another challenge has centered on how to create classroom-based exercises that translate to work conducted independently in the field. We've repeatedly observed instances of students struggling to apply methods and theory to open-ended projects outside of the classroom. One successful but time and effort costly method for addressing this challenge is to model the techniques in the field, since providing feedback regarding student performance in a timely manner is critical. A less costly option is to actively promote student reflections and peer-to-peer training to navigate challenges associated with applying techniques in the field.

One of our greatest challenges over the past decade has been managing expectations. Programmatic outcomes are discussed and understood at the administrative level, e.g., collaborating faculty and department heads, but it has been difficult to manage expectations among healthcare providers (e.g., nurses, midwives) within the tertiary healthcare facilities. Students develop and practice mission statements prior to field site work that minimize communication conveying commitments of delivery of functional medical devices. Additionally, student teams have presented at clinical department morning meetings at both the beginning and end of the clinical immersion experience and created posters and delivered presentations that have provided updates about project outcomes. Students' expectations are also difficult to manage – during the interview stage, many convey sentiments of wanting to make an impact and save lives through this short-term experience. Given that a limited number of concept solutions are fully realized as implementable health technology products, we emphasize the importance of disseminating student work and methods through design competitions, conference presentations, and journal papers.

Another major challenge to overcome in these collaborative and innovative programs is the ability to link the training phases of two disciplines, engineering and health, traditionally thought to be miles apart in many institutions. Interprofessional education everywhere, and especially across borders, is in its infancy. Issues of trust, financial transparency and sustainability present existential ethical challenges. Implementation of engineering best practices face many of the same challenges with practitioners and policymakers as does implementation science.

### 5.3. Additional Benefits

Several studies have demonstrated that the vast majority of hospitals in LICs reported difficulty when searching for qualified engineers to support their healthcare technologies [103-104]. To contribute to solving these issues, LICs need to recruit and train biomedical equipment technicians, clinical engineers, and biomedical engineers to facilitate the local design, development, and production of health technologies in LMICs. Despite their crucial role, biomedical engineering programs are rare in LICs; a study of African and North American universities found that only twenty-one universities offered biomedical/bioengineering in Africa (in only eight countries) compared to 189 in the United States alone [104-105]. In a recent study, we observed a significant discrepancy between Ghanaian biomedical engineering students' perceptions of the work of biomedical engineers (i.e., medical device innovators) and the career options they believe are available (i.e., they did not perceive there to be career opportunities in the design and development of novel health technologies, but perceived that the most likely jobs were in the sales, repair, maintenance, or procurement of hospital equipment) [107]. This discrepancy could be due to of the lack of job opportunities in medical device development and production in Ghana [108-109], leaving students to feel that while biomedical engineers contribute to the development of solutions that address health problems, they, themselves did not have access to do so in their own country. Collaborative programs such as the one described in this paper provide an opportunity to develop health technology innovators as well as potential local markets for locally designed and manufactured products.

Clinicians from LICs have noted the educational impact that they have had on student participants including the first-hand demonstration of the local design constraints and challenges associated with using and maintaining equipment and devices within LICs. Clinicians, residents, and medical students regularly provide input and guidance during the opportunity discovery and definition phases, as well as during the concept generation work performed at the field site. The unique opportunity for LIC clinicians to collaborate with engineering students through such programs as the ones described above allows them to: 1) participate in the design, design evaluation, and integration/implementation of needed devices for their special practice needs; 2) develop skills to better utilize and adapt uses for new technologies introduced into their sub region; and 3) identify optimal extant medical and surgical devices to implement at the right time and in the right way into specialty and general practice use. They also develop

skills in financial assessment and supply chain integration of new devices and products. For UM clinical trainees, benefits include participation in technology innovation, design, and evaluation, as well as the opportunity to work with multidisciplinary teams enriched with engineering students, gaining indirect exposure to differences in design processes that facilitate technology development in HICs versus LICs. These experiences challenge clinical trainees to consider alternative mindsets regarding and approaches to innovation and entrepreneurship, and have the potential to develop stand out innovators and entrepreneurs among these clinicians who would not otherwise have chosen that space.

In addition to facilitating skill acquisition among students and clinical trainees, the program has the long-term potential to impact society through the creation of medical device industry leaders and innovators familiar with LICs, appropriate technologies, and design methodologies focused on the unique constraints of LICs. Furthermore, opportunities co-discovered by engineering and non-engineering students with healthcare trainees and providers may contribute to both short- and long-term global healthcare technology agendas.

## **Conclusions**

Decades of investing in lifesaving medical devices, training health care providers at various levels, and planning strategic interventions globally have led to drastic reductions in mortality due to infectious diseases, maternal and child illness, and malnutrition. Traditional engineering design processes are technology-centric, with minimal emphasis on contextual, cultural, and stakeholder aspects of the design artifact. However, design approaches that consider local constraints, cultural contexts, and stakeholder needs, and enhance the capacity of the local workforce are particularly effective, especially within the context of health technology design in LICs. Successful design for LICs depends on understanding the broader issues associated with implementation in the early stages of the process rather than after the validation and production stages. Key components of successful front-end design involve interacting with and understanding product stakeholders and contexts of use during the development of technology product profiles. The ambiguous and iterative process of understanding stakeholders and contexts of use and translating this understanding into design decisions are challenging characteristics of design work. It is imperative that engineering students are provided with opportunities to develop these critical skills; not only in the classroom, but also “in the field”.

We have developed and implemented clinical immersion and design ethnography experiential learning experiences in collaboration with clinical and engineering partners from multiple sub-Saharan African academic institutions to support the development of human-/user- and context-centered engineering designers; specifically, students gain both theoretical, but more importantly, practical hands-on experience identifying and defining engineering design opportunities through in-depth interactions with stakeholders from diverse cultural and disciplinary backgrounds at clinical field sites. Student participants demonstrate more informed design behaviors including interviewing, requirements elicitation, and information gathering and synthesis skills. Students from UM and UG have contributed to the design of healthcare technologies to ultimately address health disparities among vulnerable populations, encouraging additional co-creative design processes that include clinicians and engineers as well as contributing to a growing field of engineers equipped to design contextually rich technologies that integrate cultural and social factors to meaningfully and sustainably meet healthcare needs in resource limited settings.

## **Acknowledgments**

We would like to acknowledge the student participants and our partners in Ghana, Ethiopia, China, Uganda, and Kenya, as well as the numerous healthcare providers that have supported our students during their clinical immersion, design ethnography, and capstone design experiences. We’d like to thank the UM Department of Obstetrics and Gynecology, UM College of Engineering, UM Department of Mechanical Engineering, UM African

Studies Center, UM International Institute, UM Multidisciplinary Design Program, UM GIEU Program, UM Center for Research on Learning and Teaching, UM librarians, and UM Laundry Services. We also acknowledge funding through a National Science Foundation CAREER grant (RAPD/GARDE-0846471), and an NCIIA (VentureWell) Course and Program grant (Development of an Undergraduate Minor Specialization in Sustainable Global Health Design). We'd also like to thank Prof. Shanna Daly, Dr. Anthony Ofosu, Mrs. Karen Brown, Mr. Kofi Gyan, and Dr. Amir Sabet Sarvestani, Ms. Caroline Soyars, and the Korybalski, Littleton, Papadopoulos, Miller, and Sterken families for their generous support.

### List of Tables

1. Illustrative sample of undergraduate participants from a subset of GHDI offerings (academic program and internship) by gender and major from 2010-2017 ..... [8](#)
2. Summary of clinical needs finding outcomes in Ghana, Ethiopia, Kenya, and China ..... [8](#)

### List of Figures

1. Global Health Design Initiative process ..... [5](#)
2. Hemafuse, blood salvage device ..... [10](#)
3. Early-stage prototype of the Visualize trainer ..... [10](#)
4. SubQ Assist prototype . ..... [11](#)

### Biographies:

**Kathleen H. Sienko** received a B.S. degree in materials engineering from the University of Kentucky, Lexington, in 1998, an S.M. degree in aeronautics and astronautics from the Massachusetts Institute of Technology (MIT), Cambridge, in 2000, and a Ph.D. degree in medical engineering and bioastronautics from the Harvard-MIT Division of Health Sciences and Technology, Cambridge, in 2007. She was a Research Engineer with the Massachusetts Eye and Ear Infirmary, Harvard Medical School, Boston, MA. She is currently an Arthur F. Thurnau Associate Professor in the Departments of Mechanical Engineering and Biomedical Engineering at the University of Michigan, Ann Arbor, where she directs the Sienko Research Group. She has led efforts at the University of Michigan to incorporate the constraints of global health technologies into undergraduate and graduate engineering design and is director of the Global Health Design Initiative and co-founder of the Center for Socially Engaged Design. Professor Sienko's educational initiatives have been recognized by the National Academy of Engineering as part of its Frontiers of Engineering Education Symposium, and she has been awarded the UM Undergraduate Teaching Award, Provost's Teaching Innovation Prize, UM Distinguished Professor Award, UM College of Engineering Raymond J. and Monica E. Schultz Outreach and Diversity Award, UM Mechanical Engineering Achievement Award, and UM Pi Tau Sigma Professor of the Term Award. Professor Sienko is a member of American Society of Mechanical Engineers, the American Society for Engineering Education, and the Institute of Electrical and Electronics Engineers.

**Maria R. Young** holds a BS degree in biomedical engineering (2014) from the University of Michigan, where she specialized in multidisciplinary global health design, and an MS degree in Human Nutrition (2015) from Columbia University. Ms. Young has significant experience using qualitative research methods and design ethnography techniques to investigate a community's health and wellness, specifically in resource limited settings. Ms. Young is

a co-founder of the organization *Visualize*, which aims to design and create novel training devices to teach midwives how to screen for cervical cancer. At Columbia, she was a graduate research assistant in the HIV Vaccine Research Unit, where she investigated barriers and facilitators to participation in trials by high-risk communities. From 2015-2017, Ms. Young served as the program manager for the Global Health Design Initiative (GHDI) at the University of Michigan and an Assistant Director at the Center for Socially Engaged Design, where she led the development of the center's Socially Engaged Design Academy (SEDA). Recently, Ms. Young worked as a research associate at Northwestern University in the Department of Obstetrics and Gynecology investigating trauma exposure among obstetrics patients and the use of a novel app for the management of gestational diabetes.

**Elsie Effah Kaufmann** is a Senior Lecturer and founding Head of the Department of Biomedical Engineering, University of Ghana. She holds a Bachelor of Science in Engineering (BSE), a Master of Science in Engineering (MSE) and a PhD in Bioengineering, all from the University of Pennsylvania, USA. After her graduate studies, she received her postdoctoral training at Rutgers University, before joining the University of Ghana in 2001. Dr. Effah Kaufmann was a member of the Planning Committee set up by the Academic Board of the University of Ghana to make proposals for establishing the Faculty of Engineering Sciences and was also a member of the three-person Implementation Committee set up by the Vice Chancellor following the submission and adoption of the Planning Committee's report. She was appointed as the first Head of the Department of Biomedical Engineering in 2006. Dr. Effah Kaufmann's teaching and research focus on tissue engineering, biomaterials and application of biomedical engineering concepts to the solution of problems in the Ghanaian context. She was the recipient of the University of Ghana's Best Teacher Award for the Sciences in 2009. She is also keenly interested in science education at all levels and has been the Host/ Quiz Mistress of the Ghana National Science & Mathematics Quiz TV Programme since 2006.

**Samuel Obed** received his MB ChB from the University of Ghana School of Medicine in 1982 and became a Fellow of the International Federation of Gynecology and Obstetrics in 1994, a Fellow of the West African College of Surgeons in 1995, and a Foundation Fellow of the Ghana College of Physicians and Surgeons in 2004. Dr. Obed was a consultant of Obstetrics and Gynecology at Korle Bu Teaching Hospital from 1995-2017 and served as the Head of the Department of Obstetrics and Gynecology from 2009-2017. Prior, he worked as a consulting obstetrician-gynecologist at the Volta River Authority Hospital in Akosombo. Dr. Obed completed external residency training at Louisiana State University and St. John Mercy Medical Center and fellowship training in advanced assisted reproductive technology at the Washington University School of Medicine. Dr. Obed was an Associate Professor of Obstetrics and Gynecology (2007-2017) and Head of the Department of Obstetrics and Gynecology (2009-2017) at the University of Ghana Medical School. He held numerous academic appointments including Program Director for the International Family Planning and Reproductive Health Fellowship and Co-Chair of the Perinatal Research Group. Additionally, Dr. Obed was a Becks Visiting Professor in the Department of Obstetrics and Gynecology at the University of Michigan in 2010 and a Distinguished Visiting Lecturer in the Department of Obstetrics and Gynecology at the New York University School of Medicine in 2014. Dr. Obed was a member of the Ghana Medical Association (1982-2017) and the Ghana Surgical Research Society (1997-2017). He served as a reviewer for multiple academic journals including the International Journal of Obstetrics and Gynecology and the African Journal of Reproductive Health. Dr. Obed authored over 50 peer-reviewed journal publications and book chapters. His research interests focused on hypertensive diseases in pregnancy, maternal mortality, gynecological endocrinology and infertility, and ectopic pregnancy.

**Kwabena A. Danso** is Professor of Obstetrics and Gynecology at Kwame Nkrumah University of Science and Technology School of Medical Sciences (KNUST SMS) and Consultant Obstetrician – Gynecologist at Komfo Anokye Teaching Hospital, Kumasi, Ghana. He received his medical training at KNUST SMS and fellowship certification in OBGYN from the West African College of Surgeons. He has held several academic leadership positions in KNUST including Chairman of OBGYN (2001-2008), Vice-Dean (2007-08), Dean (2008-11) and

Acting Provost of the College of Health Sciences (2011). Professor Danso is a member of the Ghana Medical Association, the Society of Gynecologists and Obstetricians of Ghana and the University Teachers Association of Ghana. He is a foundation fellow of the Ghana College of Physicians and Surgeons and founding fellow of the Reproductive Health and Family Planning subspecialty programme of the Ghana College. He also teaches Strategic Leadership and Management for Health Systems Transformation in the MPH/MSc programme in KNUST. He has made several academic exchange trips abroad including the University of Ulm Women's Hospital and Polyclinic, Ulm, Germany in November 2001 and the Alfred C. Beck and Rhea B. Beck Visiting Professor to the Department of Obstetrics and Gynaecology of the University of Michigan Medical School in May 2007. He was awarded an Honorary Fellowship of the American College of Obstetricians and Gynaecologists in 2012. Professor Danso's interest is in medical education and reproductive health issues in the areas of obstetric fistula, safe pregnancy and birth, unsafe abortion and vertical transmission of viruses. He has several peer review articles in local and international journals. He has contributed to several textbooks and training manuals, is the lead editor of 'Comprehensive Reproductive Health and Family Planning in the Tropics' (2014) and has had journal reviewer roles for renowned journals.

**Henry S. Opare-Addo** is a Professor of Obstetrics and Gynecology in the Kwame Nkrumah University of Science and Technology and a consultant urogynecologist in the Komfo Anokye Teaching Hospital. He is an adjunct lecturer at the University of Michigan. Dr. Opare-Addo graduated with an MB CHB in 1983 from the Kwame Nkrumah University of Science and Technology having obtained a BSc. in human biology 3 years earlier. In 1993, he received a certificate in Health Administration and Management for Senior Health Personnel from the Ghana Institute of Management and Public Administration, Legon. Dr. Opare-Addo became a fellow of the West African College of Surgeons in 1997 and the Ghana College of Physician and Surgeons in 2004. He has an interest and ongoing research in the following areas: urogynecology and female sexuality, obstetrics and gynecology imaging, and improving quality of care and prevention of maternal mortality. Dr. Opare-Addo was the principal investigator in the Komfo Anokye Teaching Hospital for the recently published World Maternal Antifibrinolytic ( WOMAN ) Trial.

**Cornelius A. Turpin** is an Associate Professor of Obstetrics and Gynecology at the Kwame Nkrumah University of Science and Technology (KNUST) School of Medical Sciences and a Consultant Obstetrician Gynaecologist at the Komfo Anokye Teaching Hospital in Kumasi, Ghana. He served as the Head of the Department of Obstetrics and Gynaecology from 2014-2017. Dr. Turpin received his BSc degree in Human Biology (1981), MB in General Medicine (1984), and ChB in Surgery (1984) from KNUST School of Medical Sciences. He became a fellow of the West African College of Surgeons in 2000 and a fellow the Ghana College of Physicians and Surgeons in 2004. Dr. Turpin received a certificate in Health Administration and Management in 2001 from the Ghana Institute of Management and Professional Administration. He is a member of the Ghana Medical Association and Society of Obstetricians and Gynecologists of Ghana. Dr. Turpin received the Beck visiting Professor Award Winner at the University of Michigan in 2017. Dr. Turpin has authored over 30 peer-reviewed journal publications and book chapters. He has an interest and ongoing research in the areas of antenatal care uptake and birth outcomes and primary postpartum hemorrhage.

**Thomas O. Konney** is a Consultant Gynecological Oncologist at Komfo Anokye Teaching Hospital and a Lecturer in the School of Medical Sciences at Kwame Nkrumah University of Science and Technology (KNUST) in Kumasi, Ghana. Dr. Konney graduated with an MD degree in 1995 from Almaty State Medical Institute. Dr. Konney became a fellow of the West African College of Surgeons, Obstetrics and Gynecology in 2008 and a fellow of the Ghana College of Physicians and Surgeons in 2016. In 2012, he completed a fellowship in Gynecological Oncology at Vivantes Klinikum, Neukolln, in Berlin, Germany and received a certificate in Health Administration and Management from the Ghana Institute of Management and Professional Administration. Dr. Konney completed a postdoctoral fellowship in Global Health in 2012 and a certificate in Gynecological Oncology in 2016, both at the

University of Michigan. He has served as a teacher, supervisor, and mentor for students at the School of Medical Sciences, KNUST since 2007 and the University of Michigan College of Engineering since 2009. Dr. Konney has ongoing research interests in the provision of obstetrics and gynecological services as well as maternal and perinatal health and female cancers. He is active in teaching and supervising postgraduate students for the fellowship programs of the West African College of Surgeons and the Ghana College of Physicians and Surgeons.

**Zerihun Abebe** is the current Provost of St. Paul's Hospital Millennium Medical College (St. Paul's). Dr. Zerihun has a proven medical, academic, and administrative track record over the past decade, which has given him the professional experience needed to strengthen growth in healthcare and medical education at St. Paul's. He earned his MD from Addis Ababa University in 2004, after which he worked as an assistant lecturer in Pathology in Mekelle University. He then completed a three-year residency and a Certificate of Specialty in Dermatology and Venereology in 2008. Before joining St. Paul's, he worked in the College of Health Sciences in Mekelle University, where he served as the Interim Chair of the Business Process Reengineering Committee. His work at Mekelle University inspired him to join St. Paul's and support the growth and transformation plan of the institution to become a thriving medical school and hospital for the public.

**Ibrahim Mohedas** is a post-doctoral researcher in the Department of Mechanical Engineering at the University of Michigan. He received his masters and doctoral degrees from the University of Michigan (Mechanical Engineering) in 2016 and a bachelor's degree from The University of Texas at Austin (2011). His doctoral research focused on the use of ethnographic techniques during front-end design. Specifically, he investigates how design ethnography can be used in the development of medical devices for low-income countries (LICs), how novices learn and implement design ethnography, what defines an expert design ethnographer, and what frameworks improve design ethnography outcomes and learning. Over the course of his doctoral research, Dr. Mohedas has conducted over 150 stakeholder interviews and over 350 hours of observations in LICs. These stakeholder interviews have been used to generate designs which meet critical needs, take into account diverse perspectives, and consider key downstream factors that often cause designs to fail (e.g., procurement, regulation, manufacturing, etc.).

**Aileen Huang-Saad** is an Assistant Professor in Biomedical Engineering and Engineering Education. Previously, Aileen was the Associate Director for Academics in the Center for Entrepreneurship, co-founder of the College of Engineering Center for Entrepreneurship, and Associate Professor of Practice in Biomedical Engineering. She was responsible for building the initial Program in Entrepreneurship for UM undergraduates, co-developing the Masters' level entrepreneurship program, launching the National Science Foundation University of Michigan I-Corps Node and creating the biomedical engineering graduate design program. Aileen has received a number of awards for her teaching and student advising, including the Thomas M. Sawyer, Jr. Teaching Award, the UM ASEE Outstanding Professor Award, the Teaching with Sakai Innovation Award, and the College of Engineering Outstanding Student Advisor Award. Her current research area is entrepreneurship and innovation in higher education. She is funded by the National Science Foundation to explore explicit and implicit learning outcomes and of undergraduate entrepreneurship courses based on the Lean Launch curriculum and the influence of the microenvironment of entrepreneurship education on the engagement of women. Aileen has a Bachelor's of Science in Engineering from the University of Pennsylvania, a Doctorate of Philosophy from The Johns Hopkins University School of Medicine, and a Masters of Business Administration from University of Michigan Ross School of Business.

**Timothy R.B. Johnson** served as Chair of Obstetrics and Gynecology at the University of Michigan from 1993-2017. He is Bates Professor of the Diseases of Women and Children; and also Arthur F. Thurnau Professor; Professor, Women's Studies, and Research Professor, Center for Human Growth and Development. His education and training have been at the University of Michigan, University of Virginia and Johns Hopkins. Prior to returning to the University of Michigan, he was on the faculty at Johns Hopkins. He is active in international teaching and

training especially in Ghana. He is author of over three hundred articles, chapters and books and has served on numerous editorial boards, study sections, professional committees, societies and boards. Doctor Johnson has received the Distinguished Service Award, the highest honor of the American College of Obstetricians and Gynecologists (ACOG), the Distinguished Merit Award, the highest honor of the International Federation of Gynecology and Obstetrics (FIGO), and membership in the Society of Scholars of the Johns Hopkins University. He is Past President of the Association of Professors of Gynecology and Obstetrics, receiving their Lifetime Achievement Award in 2012, and Editor-Emeritus of the International Journal of Gynecology and Obstetrics (official journal of FIGO) serving as Editor from 2007-2014. Doctor Johnson is an elected member of the National Academy of Medicine (formerly Institute of Medicine) and the National Academy of Science. His research interests are fetal behavior and assessment, principles of prenatal care, global health ethics and international academic capacity building.

## References

1. J Duderstadt, "Engineering for a Changing World," *Engineering Education for the 21st Century: A Holistic Approach to Meet Complex Challenges*. Ann Arbor, MI, 2008.
2. S. D. Sheppard, K. Macatangay, A. Colby, and W. M. Sullivan, *Educating engineers: designing for the future of the field*. San Francisco, CA: Jossey-Bass, 2009.
3. National Academy of Engineering. *The Engineer of 2020: Visions of Engineering in the New Century*. The National Academies Press. Washington, D.C., 2004.
4. A. S. for E. Education, "Transforming Undergraduate Education in Engineering," in *Phase I: Synthesizing and Integrating Industry Perspectives*, 2013, pp. 1–50.
5. A. J. Dutton, R. H. Todd, S. P. Magleby, and C. D. Sorensen, "A Review of Literature on Teaching Engineering Design Through Project- Oriented Capstone Courses," *J. Eng. Educ.*, vol. 86, no. 1, pp. 17–28, 1997.
6. L. R. Lattuca, P. T. Terenzini, and D. B. Knight, *2020 Vision: Progress in Preparing the Engineer of the Future*. Ann Arbor, 2014.
7. C. K. Prahalad and V. Ramaswamy, "Co-creating unique value with customers," *Strateg. Leadersh.*, vol. 32, no. 3, pp. 4–9, 2004.
8. T. Salvador, G. Bell, and K. Anderson, "Design Ethnography," *Des. Manag. J. (Former Ser.)*, vol. 10, no. 4, pp. 35–41, Jun. 2010.
9. P. Skaggs, "Ethnography in product design - looking for compensatory behaviors," *J. Manag. Mark. Res.*, vol. 3, pp. 1–6, 2010.
10. R. G. Cooper, "Predevelopment Activities Determine New Product Success," *Ind. Mark. Manag.*, vol. 17, no. 3, pp. 237–247, Aug. 1988.
11. R. G. Cooper and E. J. Kleinschmidt, "Determinants of timeliness in product development," *J. Prod. Innov. Manag.*, vol. 11, no. 5, pp. 381–396, Nov. 1994.
12. A. M. Davis, *Software Requirements - Objects, Functions, and States*, 2nd ed. Upper Saddle River, NJ: Prentice Hall, Inc., 1993.
13. A. Khurana and S. R. Rosenthal, "Towards Holistic 'Front Ends' in New Product Development," *J. Prod. Innov. Manag.*, vol. 15, no. 1, pp. 57–74, 1998.
14. N. W. McGuinness and H. A. Conway, "Managing the Search for New Product Concepts: A Strategic Approach," *R&D Manag.*, vol. 19, no. 4, pp. 297–308, 1989.
15. M. Rosenau, "Faster new product development," *J. Prod. Innov. Manag.*, vol. 5, pp. 150–153, 1988.
16. J. Kim and D. Wilemon, "Focusing the Fuzzy Front-End in New Product Development," *R&D Manag.*, vol. 32, no. 4, pp. 269–279, 2002.

17. T. Salvador, G. Bell, and K. Anderson, "Design Ethnography," *Des. Manag. J.*, vol. 10, no. 4, pp. 35–41, 1999.
18. A. E. Diaz, "The challenge of dealing with cultural differences in industrial design in emerging countries: Latin-American case studies," *Usability Int. HCI Cult.*, vol. 45559, pp. 57–64, 2007.
19. R. H. Mohtar and A. E. Dare, "Global design team: A global service-learning experience," *Int. J. Eng. Educ.*, vol. 28, no. 1, pp. 169–182, 2012.
20. T. B. Company, T. B. Company, and T. B. Company, "Industry Expectations of New Engineers : A Survey to Assist Curriculum Designers," no. January, 1999.
21. C. Wasson, "Ethnography in the field of design," *Hum. Organ.*, vol. 59, no. 4, pp. 377–388, 2000.
22. F. Kensing and J. Blomberg, "Participatory Design : Issues and Concerns," *Comput. Support. Coop. Work*, vol. 7, no. 1993, pp. 167–185, 1998.
23. L. L. Bucciarelli, "An ethnographic perspective on engineering design," *Des. Stud.*, vol. 9, no. 3, July 1998, pp. 159–168.
24. E. J. Arnould and M. Wallendorf, "Market-Oriented Ethnography: Interpretation Building and Marketing Strategy Formulation," *J. Mark. Res.*, vol. 31, no. 4, pp. 484–504, 1994.
25. M. Steen, N. De Koning, and A. Pikaart, "Exploring human centred approaches in market research and product development – three case studies," in *Proceedings of the conference on Dutch directions in HCI, 2004*, pp. 1–4.
26. P. J. Walters, "Knowledge in the making: prototyping and human-centred design practice," 2005.
27. J. Grudin and R. E. Grinter, "Ethnography and Design," *Comp. Support Coop. Work*, vol. 3, 1995, pp. 55–59.
28. S. G. S. Shah and I. Robinson, "Benefits of and barriers to involving users in medical device technology development and evaluation," *Int. J. Technol. Assess. Health Care*, vol. 23, no. 1, 2007, pp. 131–137.
29. S. R. Rosenthal and M. Capper, "Ethnographies in the Front End: Designing for Enhanced Customer Experiences\*," *J. Prod. Innov. Manag.*, vol. 23, 2006, pp. 215–237.
30. M. Steen, L. Kuijt-evers, and J. Klok, "Early user involvement in research and design projects – A review of methods and practices," in *23rd EGOS Colloquium, 2007*.
31. J. W. Moody, J. E. Blanton, and P. H. Cheney, "A theoretically grounded approach to assist memory recall during information requirements determination," *J. Manag. Inf. Syst.*, vol. 15, no. 1, pp. 79–98, 1998.
32. G. J. Browne and M. B. Rogich, "An Empirical Investigation of User Requirements Elicitation: Comparing the Effectiveness of Prompting Techniques," *J. Manag. Inf. Syst.*, vol. 17, no. 4, 2001, pp. 223–249.
33. C. Burnay, I. J. Jureta, and S. Faulkner, "What stakeholders will or will not say: A theoretical and empirical study of topic importance in requirements engineering elicitation interviews," *Information Systems*, vol. 46, 2014, pp. 61–81.
34. B. J. C. Wetherbe, "Executive Information Requirements: Getting It Right," *MIS Q.*, vol. 15, 1991, pp. 51–65.
35. S. Donoghue, "Projective techniques in consumer research," *J. Fam. Ecol. Consum. Sci.*, vol. 28, no. 1, 2010, pp. 47–53.
36. J. A. Goguen and C. Linde, "Techniques for Requirements Elicitation," in *1st IEEE International Symposium on Requirements Engineering (RE'93), 1993*, pp. 152–164.
37. R. Agarwal and M. R. Tanniru, "Knowledge Acquisition Using Structured Interviewing: An Empirical Investigation," *J. Manag. Inf. Syst.*, vol. 7, no. 1, 1990, pp. 123–140.
38. R. Luck, "Learning to talk to users in participatory design situations," *Des. Stud.*, vol. 28, 2007, pp. 217–242.
39. L. Nguyen, J. Carroll, and P. A. Swatman, "Supporting and monitoring the creativity of IS personnel during the requirements engineering process," *Proceedings of the 33rd Annual Hawaii International Conference on System Sciences*, Maui, HI, Jan. 2000.
40. C. Strickland, "Mining for information: tactics for interviewing," *IPCC 2001. Commun. Dimens. Proc. IEEE Int. Prof. Commun. Conf.*, pp. 349–352, 2001.

41. P. Ingwersen and K. Jarvelin, *The Turn: Integration of Information Seeking and Retrieval in Context*. Amsterdam: Springer, 2005.
42. T. D. Wilson, "Models in Information Behavior Research," *J. Doc.*, vol. 55, no. 3, 1999, pp. 249–270.
43. M. Tanni and E. Sormunen, "A Critical Review of Research on Information Behavior in Assigned Learning Tasks," *J. Doc.*, vol. 64, no. 6, 2008, pp. 893–914.
44. M. Alexandersson and L. Limberg, "Constructing Meaning Through Information Artefacts," *New Rev. Inf. Behav. Res.*, vol. 4, no. 1, 2003, pp. 17–30.
45. F. Hultgren and L. Limberg, "A Study of Research on Children's Information Behaviour in a School Context," *New Rev. Inf. Behav. Res.*, vol. 4, no. 1, 2003, pp. 1–15.
46. L. Limberg, "Experiencing Information Seeking and Learning: A Study of the Interaction Between Two Phenomena," *Inf. Res.*, vol. 5, no. 1, 1999, pp. 1–5.
47. J. H. McGregor and D. C. Streitenberger, "Do Scribes Learn?: Copying and Information Use," *Sch. Libr. Media Res.*, vol. 1, 1998.
48. R. E. H. Wertz, Ş. Purzer, M. J. Fosmire, and M. E. Cardella, "Assessing Information Literacy Skills Demonstrated in an Engineering Design Task," *J. Eng. Educ.*, vol. 102, no. 4, 2013, pp. 577–602.
49. J. S. Blandin, W. B. Brown, and J. L. Kock, "Uncertainty and Information-Gathering Behavior: An Empirical Investigation," in *Proceedings of the Academy of Management National Meetings*, 1974, no. 1, pp. 54–55.
50. B. Nuseibeh and S. Easterbrook, "Requirements Engineering: A Roadmap," in *Conference on the Future of Software Engineering*, 2000, vol. 1, pp. 35–46.
51. L. Macaulay and J. Mylopoulos, "Requirements Engineering: An Educational Dilemma," *Autom. Softw. Eng.*, vol. 2, no. 4, 1995, pp. 343–351.
52. I. Mohedas, S. R. Daly, and K. H. Sienko, "Characterizing novice use of design ethnography utilizing skill acquisition and learning theories," *Int. Journal of Engineering Education*, 32(3B), 2016, pp. 1364-1371.
53. I. Mohedas, S. R. Daly, and K. H. Sienko, "Student perceptions of stakeholders during capstone design," *ASEE Annual Conference & Exposition*, Seattle, WA, June 2015.
54. I. Mohedas, S. R. Daly, and K. H. Sienko, "Design Ethnography in Capstone Design: Investigating Student Use and Perceptions," *Int. J. Eng. Educ.*, vol. 30, no. 4, 2014, pp. 888–900.
55. C. J. Atman, J. R. Chimka, K. M. Bursic, and H. L. Nachtmann, "A Comparison of Freshman and Senior Engineering Design Processes," *Des. Stud.*, vol. 20, no. 2, 1999, pp. 131–152.
56. C. J. Atman, M. E. Cardella, J. Turns, and R. Adams, "Comparing Freshman and Senior Engineering Design Processes: An In-depth Follow-up Study," *Des. Stud.*, vol. 26, no. 4, 2004, pp. 325–357.
57. C. J. Atman, R. S. Adams, M. E. Cardella, J. Turns, S. Mosborg, and J. Saleem, "Engineering Design Processes: A Comparison of Students and Expert Practitioners," *J. Eng. Educ.*, vol. 96, no. 4, 2007, pp. 359–379.
58. K. M. Bursic and C. J. Atman, "Information Gathering: A Critical Step for Quality in the Design Process," *Qual. Manag. J.*, vol. 4, no. 4, 1997, pp. 60–75.
59. D. K. Sobek II and V. K. Jain, "Relating Design Process to Quality: A Virtual Design of Experiments Approach," *J. Mech. Des.*, vol. 129, no. 5, 2007, pp. 483–490.
60. I. Mohedas, S. R. Daly, and K. H. Sienko, "Gathering and Synthesizing Information During the Development of User Requirements and Engineering Specifications," *ASEE Annual Conference & Exposition*, Indianapolis, IN, 2014.
61. I. Mohedas, S. R. Daly, and K. H. Sienko, "Student Use of Design Ethnography Techniques During Front-End Phases of Design," *ASEE Annual Conference & Exposition*, Indianapolis, IN, 2014.
62. D. De Savigny and T. Adam, "Systems thinking for health systems strengthening," *Adv. Bioinformatics*, vol. 2010, no. 2, 2009, p. 268925.

63. L. Perry and R. Malkin, "Effectiveness of medical equipment donations to improve health systems: how much medical equipment is broken in the developing world?," *Med. Biol. Eng. Comput.*, vol. 49, no. 7, 2011, pp. 719–22.
64. J. F. Dyro, "Donation of Medical Device Technologies," *The Clinical Engineering Handbook*, Academic Press, 2004, pp. 155-158.
65. R. Malkin and K. Von Oldenburg Beer, "Diffusion of novel healthcare technologies to resource poor settings," *Ann. Biomed. Eng.*, vol. 41, no. 9, 2013, pp. 1841–1850.
66. P. Howitt, A. Darzi, G.-Z. Yang, H. Ashrafian, R. Atun, J. Barlow, A. Blakemore, A. M. Bull, J. Car, L. Conteh, G. S. Cooke, N. Ford, S. A. Gregson, K. Kerr, D. King, M. Kulendran, R. a Malkin, A. Majeed, S. Matlin, R. Merrifield, H. a Penfold, S. D. Reid, P. C. Smith, M. M. Stevens, M. R. Templeton, C. Vincent, and E. Wilson, "Technologies for global health," *Lancet*, vol. 380, no. 9840, 2012, pp. 507–535.
67. S. R. Sinha and M. Barry, "Health Technologies and Innovation in the Global Health Arena," *N. Engl. J. Med.*, vol. 365, no. 9, 2011, pp. 779–782.
68. Amir Sabet Sarvestani and Kathleen Sienko, "Design Ethnography as an Engineering Tool," *Demand ASME Glob. Dev. Rev.*, no. 2, 2014, pp. 2–7.
69. World Health Organization Member Profile, [http://www.who.int/workforcealliance/members\\_partners/member\\_list/who/en/](http://www.who.int/workforcealliance/members_partners/member_list/who/en/)
70. R. Richards-Kortum, L. V Gray, and M. Oden, "IBI\* series winner. Engaging undergraduates in global health technology innovation.," *Science (80-. )*, vol. 336, no. 6080, pp. 430–431, 2012.
71. Engineering World Health Duke University, <http://globalhealth.duke.edu/projects/duke-engineering-world-health>
72. Center for Innovation in Global Health Technologies Northwestern University, <http://www.mccormick.northwestern.edu/research/innovation-global-health-technologies-center/>
73. M. Oden, Y. Mirabal, M. Epstein, and R. Richards-Kortum, "Engaging undergraduates to solve global health challenges: a new approach based on bioengineering design.," *Ann. Biomed. Eng.*, vol. 38, no. 9, 2010, pp. 3031–3041.
74. Global Health Design Initiative University of Michigan <http://www.ghdi.engin.umich.edu/>
75. K. H. Sienko and C. Silcox, "Becoming the path: The HST 2003 Experience in India," *The Connector*, Harvard-Massachusetts Institute of Technology, pp. 4–5.
76. Global Intercultural Experience for Undergraduates (GIEU) University of Michigan, <https://lsa.umich.edu/cgis/gieu.html>
77. R. Snow, "Presidential Visit to Ghana & South Africa," *The Journal of the International Institute*, vol. 15(2), 2008, pp. 2–3.
78. F. W. J. Anderson, S. A. Obed, E. L. Boothman, and H. Opare-Ado, "The public health impact of training physicians to become obstetricians and gynecologists in Ghana," *Am. J. Public Health*, vol. 104, 2014.
79. P. G. Yock, S. Zenios, J. Makower, T. J. Brinton, U. N. Kumar, and F. T. J. Watkins, *Biodesign: The process of innovating medical technologies*, 2nd ed. United Kingdom: Cambridge University Press, 2015.
80. T. L. Callahan and A. B. Caughey, *Blueprints Obstetrics and Gynecology*, Fifth. Lippincott Williams & Wilkins, 2009.
81. Socially Engaged Design Academy University of Michigan, <http://csed.engin.umich.edu/socially-engaged-design-academy/>
82. M. R. Young, S. R. Daly, S. L. Hoffman, K. H. Sienko, and M. A. Gilleran, "Assessment of a novel learning block model for engineering design skill development: A Case example for engineering design interviewing," *American Society for Engineering Education Annual Conference*. Columbus, OH, June 2017.

83. K. H. Sienko, E. E. Kaufmann, M. E. Musaaazi, A. Sabet Sarvestani, and S. Obed, "Obstetrics-based clinical immersion of a multinational team of biomedical engineering students in Ghana," *Int. J. Gynecol. Obstet.*, vol. 127, no. 2, 2014, pp. 218–220.
84. M-HEAL (Michigan Health Engineered for All Lives), <http://mheal.engin.umich.edu/>
85. K. Litchfield and A. Javernick-Will, "'I Am an Engineer AND': A Mixed Methods Study of Socially Engaged Engineers," *J. Eng. Educ.*, vol. 104, no. 4, 2015, pp. 393–416.
86. J. Margolis and A. Fisher, "Unlocking the clubhouse: Women in computing," *The MIT Press*, 2001, pp. 184.
87. J. E. Perosky, R. N. Rabban, J. G. T. Bradshaw, A. P. Gienapp, A. A. Ofosu, and K. H. Sienko, "Designing a Portable Gynecological Examination Table: Improving Access to Antenatal Care in Rural Ghana," *Int. J. Serv. Learn. Eng.*, vol. 7, no. 1, 2012, pp. 1–14.
88. I. Bates, G. K. Chapotera, S. McKew, and N. Van Den Broek, "Maternal mortality in sub-Saharan Africa: The contribution of ineffective blood transfusion services," *BJOG: An International Journal of Obstetrics and Gynaecology*, vol. 115, no. 11, 2008, pp. 1331–1339.
89. C. O. Winget, T. K. Fisher, R. N. Kumar, A. H. Harrington, G. E. Henker, R. D. Davenport, A. T. Odoi, and K. H. Sienko, "Blood salvage device for use during ruptured ectopic pregnancy in low-resource countries," *Int. J. Gynecol. Obstet.*, vol. 128, no. 1, 2015, pp. 74–75.
90. Hemafuse, Sisu Global Health, <http://www.sisuglobalhealth.com/hemafuse/>
91. J. Sherris, C. Herdman, and C. Elias, "Beyond our borders: cervical cancer in the developing world.," *Western Journal of Medicine*, vol. 175, no. 4, 2001, pp. 231–233.
92. M. R. Young, J. Kramer, J. Chu, J. Hong, C. Johnston, and K. Sienko, "A Cervical Cancer Screening Trainer for Use in Low-resource Settings," *Int. J. Serv. Learn. Eng.*, vol. 11, no. 1, 2016, pp. 1–18.
93. I. Mohedas, A. S. Sarvestani, C. Bertch, A. Franklin, A. Joyce, J. McCormick, M. Shoemaker, C. Bell, T. Johnson, D. Bekele, S. Fisseha, and K. Sienko, "Assistive device for the insertion of subcutaneous contraceptive implants," *J. Med. Device.*, vol. 9, no. 2, 2016, p. 20943.
94. E. Epstein and K. Anna, "Accidental hypothermia.," *BMJ*, vol. 332, no. 7543, 2006, pp. 706–709.
95. C. F. Adams, J. D. Chirawurah, P. E. Agbekoh, and E. Effah Kaufmann, "Design of a Blood-Warming Device for Resource- Limited Settings," *Eur. J. Sci. Res.*, vol. 103, no. January, 2013, pp. 7–15.
96. I. Mohedas, G. L. Cravens, S. R. Daly, and K. H. Sienko, "Student approaches to stakeholder interactions during design: factors affecting the utility of stakeholder interactions," *J. Eng. Educ.*, 2016.
97. I. Mohedas, S. R. Daly, and K. H. Sienko, "Requirements Development: Approaches and Behaviors of Novice Designers," *J. Mech. Des.*, vol. 137, no. 7, 2014, p. 71407.
98. I. Mohedas and G. L. Cravens, "Valuing and engaging stakeholders: The effects of engineering students' interactions during capstone design," *American Society for Engineering Education Annual Conference*, 2015.
99. F. W. J. Anderson and T. R. B. Johnson, "UM Medicine: Long-term Partnerships in Ghana," *J. Int. Inst.*, vol. 15, no. 2, 2008, p. 11.
100. C. A. Klufio, E. Y. Kwawukume, K. A. Danso, J. J. Sciarra, and T. Johnson, "Ghana postgraduate obstetrics/gynecology collaborative residency training program: Success story and model for Africa," in *American Journal of Obstetrics and Gynecology*, 2003, vol. 189, no. 3, pp. 692–696.
101. M. Zenios, "Need Statement Development," in *Biodesign: the process of innovating medical technologies*, vol. 15, 2010, pp. 37–55.
102. R. Richards-Kortum and M. Oden, "Devices for Low-Resource Health Care," *Science (80-. )*, vol. 342, no. November, 2013, pp. 1055–1057.
103. H. Bekele, "Assessment on medical equipment conditions," Ethiopian Science and Technology Agency Ethiopian Scientific Equipment Center, Addis Ababa, Ethiopia, 2008.

- 104.S. Mullally and M. Frize, "Survey of clinical engineering effectiveness in developing world hospitals: equipment resources, procurement and donations." *Annual International Meeting of IEEE Engineering in Medicine and Biology Society*, 2008, pp. 1-4.
105. World Health Organization, "Human Resources for Medical Devices: The role of biomedical engineering," WHO Medical device technical series. Geneva, Switzerland, 2017.
- 106.Z. O. Abu-Faraj, "Project Alexander the Great: a study on the world proliferation of bioengineering/biomedical engineering education.," *Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. IEEE Eng. Med. Biol. Soc. Annu. Conf, 2008*, pp. 2873–2876.
- 107.I. Mohedas, E. E. Kaufmann, S. R. Daly, and K. H. Sienko, "Ghanaian undergraduate biomedical engineering students' perceptions of their discipline and career opportunities," *Glob. J. Eng. Educ.*, vol. 17, no. 1, 2015, pp. 34–41.
- 108.H. D. Banta, "Medical technology and developing countries: the case of Brazil.," *Int. J. Health Serv.*, vol. 16, no. 3, 1986, pp. 363–373.
- 109.J. Pena-Mohr, "Distributing and transferring medical technology: A View from Latin America and the Caribbean," *Int. J. Technol. Assess. Health Care*, vol. 3, 1987, pp. 281–291.