ASEE 2022 ANNUAL CONFERENCE
Excellence Through Diversity
MINNEAPOLIS, MINNESOTA, JUNE 26TH-29TH, 2022 ASEE

Paper ID #37290

Work in Progress: Development of Virtual Reality Platform for Unmet Clinical Needs Finding in Undergraduate Biomedical Engineering Design Programs

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Unmet clinical needs finding and clinical immersion programs have been widely used in higher education [1-3]. Unfortunately, they have only been offered to a select number of students (e.g. 15-20 students) due to the limited space and extensive safety protocols required for students to access hospital operating rooms. Furthermore, in the era of COVID-19, access for non-essential personnel to shadow physicians in hospitals has become increasingly difficult; combined with increasing engineering class sizes across the country, opportunities for undergraduate students to experience critically formative clinical immersion is scarce if not impossible. This situation has led to an inequitable education for students in undergraduate biomedical engineering (BME) programs. To fully embed BME students into the clinical flow, they must develop an understanding of the customer needs and daily workflows of those who will utilize their engineering solutions [4]. Without an understanding of how physicians utilize these technologies for both diagnoses and treatment in their daily workflow, our students are placed in a disadvantageous position that could negatively affect medical device innovation as a whole.

To remain competitive in the medical device landscape, BME undergraduate students must be adequately trained to identify and unpack unmet clinical needs through observation and experience. To deal with challenges of accessibility and remote learning, few institutions have utilized online video recordings to provide students with this experience [5-6]. However, these videos fail to provide similar levels of immersion than experiencing clinical environments in person, nor do they allow students to visualize the full spectrum of healthcare workers and equipment that support the surgical procedure [7-8]. Hence, there is a clear need to develop technological solutions that not only satisfy such educational demands, but also enhance the students' experience by developing a more effective remote learning content.

While early research suggests that using virtual reality (VR) for student learning has mixed results [7], more recent comparative analyses across VR and video recording education has found that students who learned from VR had a higher positive effect on knowledge transfer and self-efficacy than those who learned through video recordings [8]. This is likely because VR generates an increased sense of presence [9-10], which allows students to interact with the environment through bodily movements and gestures, improving both procedural and declarative knowledge [11-12]. This embodiment in an interactive virtual environment wherein the user has some measure of control over the experience amplifies immersion and, subsequently, presence by giving rise to a greater sense of agency; the heightened sense of presence and agency can provide students with a more developed understanding of educational content and immerse them in potential future workplaces, giving them a better introduction to their profession [13]. Therefore, to meet the educational demands previously mentioned, the authors are developing a clinical immersion program using VR experiences for undergraduate BME students, allowing them to perform unmet clinical needs finding and screening prior to their senior capstone course [14].

Starting in the Spring of 2022, the Department of Biomedical Engineering at the University of California Irvine will be offering a novel VR unmet clinical needs finding program open to upper division undergraduate students of all engineering disciplines. Our content is comprehensively informed by physicians, nurses, and allied health professionals, and is inclusive in that it can be easily accessed online by any device with a web browser: phone, tablet, computer, or VR headset. By creating a hybrid online course that will serve approximately 150 students utilizing VR immersive environments, videos, physician interviews, learning modules, and in class group work and activities, our goal is to train students to evaluate unmet clinical needs with viable commercialization possibilities, develop effective team working skills, and to use and adapt current clinical and behavioral research tools to improve healthcare [15]. To that end, this course will consist of four facets.

1. *Technical Skills Development Through Reverse Engineering*: To understand how medical devices are designed from an engineering standpoint, at the start of the course, student teams will reverse engineer a medical device of their choosing. After, they will then be asked to understand and detail the following: 1) the device's use case (e.g. location of use, who the end user is, how often it needs to be used and how long), 2) detailed understanding of how it technically operates, 3) specific design decisions (e.g. material selection, safety mechanisms, electrical and software requirements), 4) modes of failure, 5) usability, and 6) ways to improve the design. Each team member will present their perspective on the medical device's design from their area of specialization. For example, an electrical engineer would describe the circuit design and electrical parameters tested, while the computer scientist would describe the user interface, data collection, and processing requirements in the software.

2. *Virtual Unmet Clinical Needs Identification*: Next, students will be asked to view the immersive VR clinical experiences using VR headsets that will be available for loan from the school's library or through their own laptops and phones. They can also view the experiences and other content through any device that has access to a web browser, such as through a smart phone with Google Cardboard (< $15, Google VR, Mountain View, CA), . These VR experiences consist of a 360-degree panoramic view of the clinical environment and use of the engineered medical devices learned from the above module with a visualization of the primary physician's perspective. See [16] for an example of a VR clinical experience that can be viewed on any web browser. Students will also be provided with the resources necessary to identify key medical devices used during the procedure, as well as an overview of the procedure itself beforehand. Upon completing their virtual experiences, students will then attend physician-led lectures and be asked to watch recorded interviews with physicians, therapists, nurses, and staff relevant to the viewed VR experiences.

3. *Unmet Clinical Needs Evaluation*: After covering the various educational content, students will identify potential unmet clinical needs that require engineering principles to design a solution, and will form teams based upon their interests and active learning modules designed to enhance team cohesion and effective teamwork [17]. They will then have to select needs they believe is the most viable based on several activities drawn from the work of Yock et al [18]: 1) evaluation of the market landscape, 2) intellectual property strategy and barriers, 3) clinical strategy and barriers, 4) regulatory strategy, and 5) reimbursement strategy. To evaluate the solutions and select the 3 most viable and marketable, students will maintain an "innovation notebook" that will describe their observations, discussions, and debriefing sessions performed within the classroom.

4. *Engineering Solution and Market Analysis*: Once the teams have chosen a solution to pursue, they will go through guided market analysis learning models and develop a business model canvas [19] to identify the following: key partners, key activities, key resources, value propositions, customer relationships, channels, customer segments, cost structure, and revenue streams. They will also develop an engineering design strategy: software and hardware engineering design requirements, manufacturing and assembly requirements, materials and design verification and validation procedures, failure mode and effect analysis, and FDA and reimbursement strategy. The business model canvas and engineering design documentation will culminate in a final report and in class presentation that will be iterated upon during their senior year capstone program.

To assess and further develop the efficacy of our VR experiences throughout the duration of this project, we will be employing a phenomenological framework commonly adopted by VR researchers [20], [21], [13] when collecting and analyzing user feedback. Since human consciousness is susceptible to mental, environmental, and bodily sensations, a phenomenological framework directs our attention to interactions between the users and the virtual environment they are immersed in [13]. Thus, our students will complete questionnaires regarding their experience engaging with our virtual content before, during, and after taking the course alongside participating in one-on-one interviews; specifically, we will be looking for expressions' indicative of the users' sense of presence, embodiment, agency, and psychological interest and engagement. To more effectively analyze the users' phenomenological responses to our virtual environments and video content, we will employ two sets of hardware for data collection. For viewing through a monitor, we will be using the Tobii Eye Tracker 5 [22] for its ability to detect what the user is looking at in the video and for how long they look at each respective element. For the VR experiences, we will be using the HP Omnicept Reverb G2 headset [23] for the suite of biometric sensors it is equipped with that track the following data sets: heart rate, heart rate variability, eye tracking, pupil dilation, accelerometry, mouth expressions, and overall cognitive load [24]. By collecting narrative data on the users' subjective experience alongside their unique physiological data, we believe our methodology will allow us to identify the features needed for creating more pedagogically effective content.

To assess the program's overall efficacy in improving workforce-ready and entrepreneurial skills, students who took the course during their junior year are required to enroll in the BME BioENGINE program during their senior year. In this course, the researchers will assess the utilization of the solution they developed in our program, its marketability, and whether it can be expanded to become a successful start-up company or used as a demonstration of the students' skills for potential employers. To this end, we will track the students' intellectual property applications through record of invention filings, along with their career position after graduation (e.g. start-up formation, industry position, graduate or medical school, etc.) using a post-survey questionnaire. Lastly, through the Teaching and Learning Research Center, the researchers will perform a formative and summative evaluation of the components of the clinical immersion program to allow the instructors to refine the program's learning modules and activities, such as the optimization of the duration of the VR experiences and comparison to standard videos of procedures. This will be done through both quantitative (surveys with student and faculty participants) and qualitative methods (document analyses, ethnography assessment techniques [25], and focus groups with student and faculty participants).

In this post-COVID19 world, there is a clear lack of resources to support previous methods of unmet clinical needs finding. Here we present a solution that can be scaled to any size due to its accessibility across a range of devices; and, moreover, one which should enhance the students' learning experience by creating VR content which amplifies the phenomenological sensations of embodiment, presence, and agency. If proven successful, the proposed VR clinical immersion course will provide access to hospital procedures to *all* BME and medical students at a large scale while increasing the pedagogical effectiveness of the educational materials by developing more robust remote learning content.

Acknowledgements:

Research reported in this publication was supported by the VentureWell Faculty Grant Program (Award No. 19823-19) and the National Institute Of Biomedical Imaging and Bioengineering of the National Institutes of Health (Award No. R25EB031116).

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