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Board 5: WIP: An Interdisciplinary Project Development Pipeline Connecting Undergraduate Biomedical Engineering and Medicine Students

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Work in Progress: An interdisciplinary project development pipeline connecting undergraduate biomedical engineering and medicine students

Introduction:

Modern engineers need to match technical competence with global and competitive awareness [1]. In biomedical engineering (BME) specifically, the development of these abilities informs student capacity to design, innovate, translate, and commercialize solutions to impact an end-user. To support these efforts, clinical immersion experiences were developed and introduced in the early 2010s. The purpose of these experiences is to immerse students in clinical environments for the observation, documentation, and identification of clinical needs through a user-centered design process, which is essential to the design of impactful and long-lasting solutions [2, 3]. Clinical immersion content and implementation differs between programs, but generally occurs through short-term, structured programs or individual courses [4-8, 15]. At the University of Illinois at Chicago, we developed a six-week summer clinical immersion program (CIP) for rising-senior BME students [9], and later, for interdisciplinary teams of medical and BME students [10]. However, many clinical immersion experiences, including our own, were limited in scope, and lacked connection to subsequent steps of the user-centered design process following needs identification. To address this disconnect, some programs integrated clinical immersion into design curricula [11-13]. Similarly, our CIP also incorporated initial solution concepting based on identified needs [14]. Students found this inclusion meaningful as it took them beyond needs identification and into concept discussion and preliminary solution ideation accommodating a multitude of users [15]. Nevertheless, these initiatives did not connect CIP to broader BME design courses or their learning objectives.

To address this, we propose a distributed and interdisciplinary pipeline for sustainable student-driven innovation. The first aim of this pipeline is to enhance senior design (SD) project preparedness by 1) introducing a new physical prototyping course to develop and practice essential fabrications skills, and 2) revising CIP to better validate needs for the new pipeline’s longitudinal process. The second aim is to leverage interdisciplinary collaboration to enhance medtech device design by 1) using CIP as a catalyst to identify and validate needs for use as SD projects and 2) continuing longitudinal development beyond SD with medical student innovators from our four-year cocurricular Innovation Medicine (IMED) program for medical students. Transitioning projects from CIP to SD, by students with training in prototyping, and then to medical capstone has substantial benefit including the ability to retain technical progress and pursue further development that would not otherwise be possible by one capstone experience alone (e.g., publication, execution of limited studies, filing of intellectual property). Together, the pipeline enables the longitudinal development of projects across disciplines and aims to enhance BME student training in a comprehensive user-centered design process.

Methods:

These aims will be executed through the development of 1) a new physical prototyping course, 2) a revised CIP, 3) an advanced BME SD course sequence, and 4) a longitudinal development process with IMED students. Appendix Table 1 compares current and proposed curricula.

New Prototyping Course: Despite teaching and practicing circuit design, programming, CAD, and 3D printing, our BME students have no curricular exposure to other forms of mechanical prototyping. To address this deficiency, we developed and implemented a new elective Physical Prototyping for Design course. The purpose of this course is to introduce and practice basic fabrication techniques that are useful for both SD and students' engineering competencies in general. The class was first offered in Fall 2022 (3-credit hybrid lecture-lab) in a College of Engineering Makerspace where students had supervised access to machining equipment and tools. Students gained experience working with different materials (wood, metals, hard plastic, soft plastic, fabrics), fasteners (screws, bolts, rivets), measurements tools, molding techniques, and related equipment (bandsaw, drill press, laser cutter, router) to fabricate toolboxes.

Revised Clinical Immersion Program: The history of our CIP has been described previously [15]. Briefly, it's a highly-selective , six-week, interdisciplinary summer immersion internship between rising-senior BME and -second-year IMED students, typically 8-12 students each. The purpose of CIP has been to identify clinical needs, but little validation of the need was conducted beyond primary observation, stakeholder analysis, and synthesis. Further validation is important, especially given the longitudinal nature of the pipeline is designed to enable the pursuit of advanced development (e.g., publication, intellectual property). Beginning in the summer of 2022, we revised CIP to better validate the needs identified in CIP according to the IDEO model for innovation, which examines project desirability, feasibility, and viability [16, 17]. Desirability reflects real-world user needs as assessed by primary observation, synthesis, and stakeholder analysis culminating in needs statements similar to our previous versions of CIP. Feasibility assesses the ability of a team to create a solution, including the availability of technology and the evaluation of prior art. Viability leverages market analysis and value proposition to determine the potential of a solution to make a long-term market impact. The most compelling needs, being validated by this model, were submitted to BME SD for development. The adoption of this IDEO model in CIP reflects a more entrepreneurial- and innovation-oriented mindset for the evaluation of clinical needs.

Revised and Advanced Senior Design: BME SD is a required, continuous, two-semester, Fall-Spring academic sequence. Historically, SD accepted projects from a variety of project sponsors, including faculty within and outside engineering, clinicians, and local industry. Accordingly, a substantial portion of the SD sequence (~25%) was devoted to conducting relevant background research, analyzing commercial alternatives, evaluating intellectual property, and crafting a needs statement to represent the scope of the work. Beginning in the Fall of 2022, we revised SD to also accept projects based on needs identified in CIP, which allowed us to remove or redistribute the aforementioned didactics and paired assessments from the class. With this revision to SD, we more aggressively pursued the remainder of the design process. Namely, the prototyping phase of SD, which was historically in the second semester of the sequence, was accelerated into the first. This allowed, for the first time in our program, elevated prototype fidelity along with the inclusion of both verification and validation during the second semester of the SD sequence. Notably, solicitation of non-CIP projects was also updated so all SD projects started at the same point in our design process. We also planned for the IMED students from CIP to serve as clinical liaisons for teams working on projects from CIP. IMED student liaisons are an important reference point to ensure clinical relevance during prototyping and validation testing. Traditional learning objectives of our SD class were updated to include validation.

<u>Longitudinal Development with IMED Students:</u> IMED students participate in project-based skills training to prepare them to be physician innovators. IMED students participate in CIP, BME SD, and their own capstone project in their third and fourth years. Ideally, transitioning projects through the pipeline (i.e., identified in CIP, developed in SD, and transitioned to IMED capstone) will dramatically accelerate the progress of innovation because much of the technical development will have already occurred. IMED students continuing projects can strengthen the value proposition of the project, perform further verification testing, perform advanced and additional validation testing with clinic and patient access under a clinical mentor, continue working with our technology transfer, prepare a manuscript on the solution, and facilitate licensure agreements over the two full remaining years of their training.

<u>Results/Discussion:</u>

Inspiration for the development of a formal pipeline comes from an initial piloting in 2019. A project identified during CIP by students in ophthalmology revealed a need related to the collection of tear film samples. This experience formed the basis for the development of a solution in SD the following Fall; a prototype was developed and verification testing was used to demonstrate alignment between design inputs and outputs. The device consisted of an electromechanical suction mechanism paired with flexible tubing to collect tear film samples. Project development was continued by two IMED students who originally helped identify the problem in CIP. The students, through further clinical observation and testing, identified unintended usage of the device and were able to develop a subsequent design to better meet clinical need. A provisional patent has been filed and IRB approval for clinical data collection and longitudinal development has been obtained.

Implementation of the pipeline began in Summer of 2022 with CIP, and continued into the Fall with the prototyping course and SD. At the time of writing, three projects from CIP (of five possible, originating from cardiology, ophthalmology, and neurosurgery) were transitioned into SD. Of these three, two retained at least one BME student from CIP in that department. In our revised SD, all teams developed a functional prototype, performed verification testing, and are currently engaged in validation testing. Anecdotally we find that CIP students who transitioned to SD tend to demonstrate enhanced professionalism and are more apt to empathize with and understand the needs of project sponsors. For example, one team with CIP students working on a device for improving hysteroscopy proposed and developed a physiologically appropriate similar cervical model for validation testing with OB/GYN physician that demanded advanced empathy. The structure for IMED liaisons requires more definition. Twelve students enrolled and completed the prototyping course in Fall of 2022, ten being enrolled in SD and two having previously completed the sequence. In future offerings, emphasis on enrollment of students prior to SD will be placed. Continuation of projects through this pipeline defines a potential for longitudinal innovative design work across disciplines, addressing several of the challenges that are present in the previous processes. The output from such a pipeline promises to be of superior quality compared to the output from any single stage of development.

Appendix

Table 1. Comparison of current to proposed pipeline curricula

	Major Outcomes/Deliverables/Processes	
Class	**Current**	**Proposed**
Physical Prototyping Class	• Does not exist	• Junior level introduction to physical prototyping • Establish competencies in woodworking, plastics, metals needed for senior design
Clinical Immersion Program	• Identification of unmet clinical needs • Preliminary solution conceptualization	• Identification and validation of clinical need • Generate needs statement and design criteria for senior design
Biomedical Engineering Senior Design	• Literature review • Needs statement development • Develop design requirements • “Low-fidelity” prototyping • Prototype iteration • Verification testing	• Develop design requirements • Quantified brainstorming for concept generation and selection • Functional prototyping • Verification testing • Validation testing • Generate documentation and materials for continued development by IMED students
Innovation Medicine (IMED) Capstone	• Clinical problems sourced independently by student teams • Independent solution development • Open-ended outcome	• Refine prototypes from senior design • Additional verification testing • Enhanced validation testing (Institutional Review Board) • Intellectual property filing including invention disclosure and possible patent conversion • Peer review publication
Comments	Product development processes and classes are discrete and discontinuous, with inconsistent and limited outcomes	Instruction and product development process is continuous across classes and disciplines, permitting enhanced and more standardized outcomes

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