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Work-In-Progress: Clinical Immersion and Team-Based Engineering Design

Dr. Jennifer Kadlowec, Rowan University

Jennifer Kadlowec is Professor and Chair of Mechanical Engineering at Rowan University, Henry M. Rowan of College of Engineering. She is interested in design education in mechanical and biomedical areas.

Dr. Tom Merrill, Rowan University
Dr. Robert Alan Hirsh, Cooper University Hospital

I am an Anesthesiologist by training. I have an abiding passion for non-invasive physiological monitoring technology, and I have several patents in this field. I am also an active Radio Amateur, WB2HRR.

Mr. Sameer Sood, Rowan School of Osteopathic Medicine

I see feasibility, potential, connections and the means for making something happen. My undergraduate engineering experience enhanced my sense of logic and persistence to solve the seemingly unsolvable. My entrepreneurial instincts led me to engineer medicine and become an inside navigator of the healthcare system so that I can eventually affect change and promote progress with my unique perspectives as a practicing physician. Lastly, my compassion for just patient care and desire to find root cause, sustainable fixes versus a reliance on ”band aid” pills has led me to the primary care side of medicine and innovation.

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INTRODUCTION

A clear need exists to streamline healthcare to reduce costs while enhancing patient care and develop more cost effective and safer medical devices. To meet this need, we must increase the number and the quality of bioengineers trained to identify and solve healthcare problems, and develop solutions through biomedical engineering education experiences.

Improving team-based design experiences driven by new projects drawn from unmet clinical needs is a strategy to train engineers while simultaneously addressing healthcare problems. Design experiences are core to engineering education and result in deeper understanding for students to identify and solve problems.[1,2,3] These as well as practical aspects of eventual commercialization and healthcare intricacies are a necessary part of student training to meet health, medical device, and patient needs while also controlling costs.[4]

Thus, to improve student learning and design capabilities, a training process occurred through a newly developed Clinical Immersion and Team-Based Design Program at Rowan University. The **first aim** was to develop and deliver an in depth biomedical engineering summer experience, involving clinic immersion and practical training on med-tech innovation, called the Clinical Bioengineering Scholars Program. Our **second aim** was to enhance our existing capstone design experience with new design projects to be designed and developed, which were discovered through the needs finding and needs specification process during the summer immersion.

METHODS

A team of engineering and medical faculty developed a program to improve team-based design education for Scholars (rising juniors, seniors and graduate students). The program consists of a new immersive summer training program using clinical mentorship at a partnering hospital and results and new projects drawn from unmet clinical needs to be carried out during the capstone design course.

The program was based on the Biodesign process, an experiential method based on three I's: Identify, Invent and Implement.[5] In the summer experience, the students worked primarily in the Identify phase as they completed needs finding, needs filtering and needs specification statements. Faculty prepared the Scholars the first week with best practices for observation, problem identification and needs statement generation in the clinical setting to make sure that the time spent in clinical immersion was effective at identifying patient care problems. Physiology training provided the students with awareness, basic understanding, and the resources to discuss and research common patient diseases and disorders they may come across during clinical immersion. Students were also assigned Responsible Conduct of Research Training.[6]

Scholars spent two weeks immersed at Cooper University Hospital, where they shadowed on rounds on medical and surgical floors and in Intensive Care Units; participated in discussions with doctors, nurses, technicians, hospital staff, secretaries, and patients; attended Grand Rounds; and were present in Operating Rooms and Cardiac Catheterization Laboratory. Scholars followed a three-step process: 1) observe clinical processes, 2) identify problems associated with that process, and 3) formulate a need statement. Each Scholar maintained an "innovation notebook" to ensure that observations were accurately captured.[5] For a few hours at the end of each week, engineering and clinical faculty met with the Scholars to discuss their observations. Through discussions, debriefing sessions, and written assignments**,** the faculty team facilitated students in identifying problems and defining needs, in preparation for writing needs statements and brainstorming potential solutions.

During weeks 4 through 6 of the summer, the focus turned to the second "I" in the Biodesign process: invention. In Week 4, Scholars began to translate problems observed during immersion into need statements that do not embed solutions and do not have improper scopes: too big or too small. Since the origin of inventing is idea creation or "ideation", best practices on group and individual creative thinking were provided. Translation also depends on converting potential solutions into actual products with intellectual property protection. To help the students appreciate this practical aspect, intellectual property overview was provided, which included: the anatomy of a patent, determining patentability, licensing, patent ownership, overall patent strategy, and intellectual property costs. In Weeks 5 and 6, Scholars dove further into the practical ideas of translation, which included regulatory basics, business perspectives and U.S. medical device reimbursement. Small business, FDA consultants, clinicians, and a bioengineering medical student provided guest lectures and discussion forums for the Scholars. Also during this time, the initial unmet clinical needs were filtered into a preferred set worth developing.

In the final weeks of the program, the Scholars developed final deliverables: needs specifications, project plans and posters, for three needs. These needs were chosen based on areas of clinical need, cost effectiveness, interest and feasibility for milestone completion in capstone design during the academic year. Scholars met with faculty to gauge potential solutions from the basic science and clinical perspectives. The summer program ended with a final Scholar symposium of projects, reflections of the Scholar experiences and plans for academic year projects. Table 1 summarizes the 2014 Rowan Bioengineering Scholars Program.

Table 1: Summer 2014 Rowan Bioengineering Scholars Program

Week	Topic	Deliverable
1	Overview of program and Basic physiology	Real-world Medtech Analysis
2&3	Clinical Immersion	Generate List of Needs
4	Concept Generation and Intellectual Property Basics	Formulate Needs Statements
5	Regulatory and Business Perspectives	
6	Needs Specific Physiology and Clinical Feedback	Needs Survey for Clinicians
7	Specifications and Prototyping	Needs Specifications and Engineering Clinic Plans
8	Closing Presentations	Poster Presentations

In the fall semester, two of the three projects continued as capstone projects. At Rowan University, capstone (Junior/Senior Engineering Clinic) projects are inspired by a mix of industry-sponsored activities, professor research activities, professional society competitions, service learning activities, and student or faculty led entrepreneurial ideas and are conducted by teams of junior and senior students. A unique aspect of the projects that were fostered from the summer program is that they were student discovered during the immersion process, rather than industry, research and/or faculty driven like many capstone experiences.

OUTCOMES / RESULTS

Two primary deliverables in the summer program were completed in pairs for each of three different needs. First, the Scholars created a need specification statements that included: defining the problem, explaining the significance of the problem, describing the physiology of the problem, describing how the problem is currently approached, explaining the issues with these approaches from all three observational perspectives, summarizing new approaches on the horizon, and listing the constraints that any future solution will have to meet. Second, the Scholars generated three potential solution concepts as well as a preliminary product development plan that reflects FDA design control and regulatory best practices. Plans included realistic timelines considering the necessary research, experimentation and an iterative design process.

Of the three plans that were developed during the summer program, two formed the basis of projects to be carried out during the academic year. Two Scholars, who worked on each of the needs specifications and development plans in the summer, continued on the project during the academic year and served as the student team lead. Other fellow Junior and Senior students were recruited based on interest and needed skill sets such that each of the two teams consist of three to five students. Each team was also led by one to two faculty advisors with input from others as needed and given a budget from NIH and VentureWell funds, which is similar to the structure of other capstone projects. The first project involved a novel implantable cardiac defibrillator and the second involved developing biodegradable catheters using silk. Each project and potential solution demonstrates an understanding of health and human systems and the design process gained throughout the immersion program.

CLOSING COMMENTS

A team of faculty have designed and implemented a first offering of a Clinical Summer Immersion program, and two projects are currently in progress based on discovered clinical needs. As the program continues over the next years we envision that increased scholarly endeavors, industrial partnerships and entrepreneurial activities by faculty and students will provide future support and enhancement for these programs in preparing a bioengineering trained workforce. Assessment is in progress for this first cohort. Pre and post surveys were conducted in order to assess self-confidence and attitudes about bioengineering design experiences and attainment of biodesign and ABET objectives. Projects, invention disclosures and patents will be tracked to further measure impact.

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