Paper ID #19437

Clinical Immersion and Team-Based Design: Into a Third Year

Dr. Jennifer Kadlowec, Rowan University

Jennifer Kadlowec is Professor and Department Head of Mechanical Engineering in the Henry M. Rowan of College of Engineering, Rowan University, Glassboro, NJ. She has been an active member of ASEE since 1998. She joined as a graduate student, after working on an engineering education project and presenting that work and student chapter activities at annual conference. As a faculty member, she regularly publishes and presents at the ASEE Annual Conference. Her interests are in design education and assessment in mechanical and biomedical engineering. She previously served ASEE in leadership roles in the ERM and Mechanics Divisions and as a PIC-III Chair.

Dr. Tom Merrill, Rowan University

Dr. Tom Merrill's research interests include energy systems, biotransport modeling, and medical devices. Prior to Rowan University, Dr. Merrill worked for thirteen years at a number of places including United Technologies Carrier, Abiomed, Wyeth Research, MicroDose Technologies, and at a medical device start-up company called FocalCool. He received his degrees in Mechanical Engineering from Penn State (Ph.D.), the University of Michigan (M.S.), and Bucknell University (B.S.). He currently teaches thermodynamics, heat transfer, fluid mechanics, and biofluids.

Mr. Sameer Sood, Rowan University School of Osteopathic Medicine

Sameer's goal is to become an inside navigator of the healthcare system so he can eventually affect change and promote progress with his perspectives as a practicing physician. His desire to find root cause, sustainable fixes versus a reliance on "band aids" has led him to the primary care side of medicine and innovation.

Dr. Jane Greene Ryan
Dr. Anilchandra Attaluri, Department of Mechanical Engineering, Pennsylvania State University-Harrisburg
Dr. Robert Alan Hirsh, Cooper Medical School of Rowan University

Clinical Immersion and Team-Based Design: Into a third year

ABSTRACT

A need exists to train undergraduate engineering students to indentify and solve healthcare problems of today and the future. A team of faculty has been contributing to that need by educating students in a summer Clinical Immersion and Team Based Design program at a mid-Atlantic University. The summer program involves the Biodesign Process, physiology basics, clinical immersion, intellectual property basics, regulatory basics, business perspectives, and development of best practices. The program participants' (or Scholars') deliverables included need statements, specifications, and guidelines to pursue as capstone design projects. A brief overview of the program content and structure is presented in this paper. Assessment of Scholar outcomes are also presented and discussed as well as future plans for the program.

INTRODUCTION

Health care spending represented 17.8 percent of the United States economy in 2015.[1] Innovations are needed in the healthcare system to enhance patient care and health, while reducing costs. Educating quality bioengineers trained to identify and solve healthcare problems will prepare them to develop cost-effective solutions.

Our strategy involves team-based design experiences driven by new projects drawn from unmet clinical needs is the strategy used here to train engineers while simultaneously addressing healthcare problems. Design experiences are core to engineering education and result in students having a deeper understanding and ability to identify and solve key problems.[2,3,4] Practical aspects including patient care, technology commercialization and healthcare intricacies are also a necessary part of student training to meet health, medical device, and patient needs while also controlling costs.[5]

To improve student learning and design capabilities, a training process involving Clinical Immersion and a Team-Based Design Program. Funding came from the National Institutes of Health and VentureWell funds. The program at our mid-Atlantic University is similar to others having a summer immersive experience and connection to a design course.[6,7]

A summer experience was developed for Summer Scholars and consisted of an overview of the Stanford Biodesign Process, physiology basics, clinical immersion, intellectual property basics, regulatory basics, business perspectives, and product development best practices. Deliverables included need statements, specifications, and project development plans. The overall process continued with capstone projects inspired by the identification and specification of the unmet clinical needs discovered by Scholars together with engineering and medical faculty.

This paper provides an overview of the program and summer experience. This also includes an evolution of the summer program, including some changes made based on feedback from the Summer Scholars and Instructors. Additionally, assessment of program outcomes are presented and discussed based on Scholar survey results. Future work and some next steps are provided.

PROGRAM OVERVIEW

A team of engineering and medical faculty developed a program to improve team-based design education for Scholars (undergraduate and graduate engineering students). The first aim was to develop and deliver an in-depth biomedical engineering summer experience, involving clinical immersion and practical training on med-tech innovation, called the Clinical Bioengineering Scholars Program. The second aim was to enhance the 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. An overview of the program was previously described.[8,9]

Briefly, the program was based on the Biodesign process, an experiential method based on three I's: Identify, Invent and Implement.[10] In the summer immersion, Scholars worked primarily in the Identify and Invent phases as they completed needs finding, needs filtering and needs specification statements. Faculty prepared the Scholars during the first week with best practices for observation, problem identification needs statements, and need specification statement generation in the clinical setting. Faculty also provided physiology training and Responsible Conduct of Research Training.[11]

A change from the first year involved increasing Scholar immersion at a mid-Atlantic Hospital from two weeks to three weeks. During immersion, they shadowed on rounds on medical and surgical floors: Trauma, Emergency Medicine, Intensive Care and Neonatal Intensive Care Units. Scholars also participated in discussions with doctors, nurses, technicians, hospital staff, secretaries, and patients. 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.[8] For a few hours twice 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 need specification statements and brainstorming potential solutions. The increased immersion time allowed the Scholars to get a more in depth look at problems, improving their understanding of the care path context and disease state fundamentals.

Another important change involved recruiting medical students to work with engineering students, building stronger Scholar teams. This elevated engineering student understanding of clinical language, and helped medical students better understand engineering design concepts.

During the final weeks of the summer program, the focus turned to the second "I" in the Biodesign process: invention. Scholars translated problems observed during immersion into need statements. Translation also depends on converting potential solutions into actual products. Consequently, an overview of intellectual property, FDA regulations, and business perspectives, both large and small, were shared. These topics were covered in a shorter period and revisited in lectures during the academic year coinciding with the project developments at the time. Also, unmet clinical needs that were identified were filtered into a preferred set worth developing.

In the final weeks of the summer program, the Scholars developed final deliverables: needs specifications, project plans and posters, for several identified 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. These selected needs provided the basis to enhance the existing capstone design course (Engineering Clinic) during the academic year with new design projects to be developed, discovered through the needs finding and needs specification process during the summer immersion. This year-long cycle and the specific topics in the summer immersion and academic semesters are summarized in Figure 1.

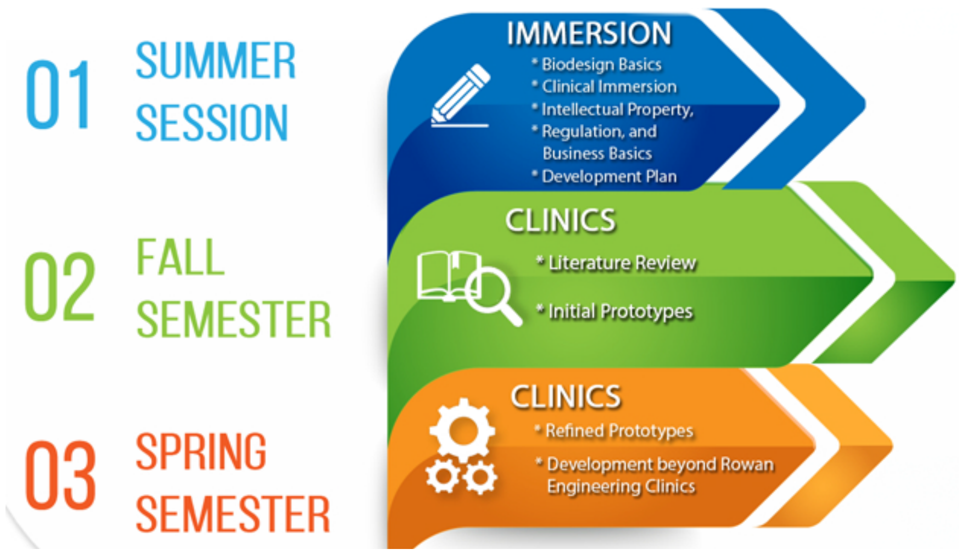

Figure 1 – Biodesign through Clinical Immersion and Capstone Design course[12]

The authors want to determine over the course of the past two years of the program the effect on Scholar attainment of program and ABET outcomes and objectives, level of interest in bioengineering fields, and likelihood to pursue bioengineering graduate studies or careers. Further the authors wanted feedback from Scholars to further improve the program going forward.

METHODS

In each summer immersion experience, participants (Scholars) from the first two years of the program, Summer 2014 and 2015, were included. Participants were recruited from students at the mid-Atlantic University where the program was offered. Priority was given to students with interests in Bioengineering and/or Entrepreneurship and seniors and graduate students, per the intentions of the granting agency and proposed project. In the Summer 2014 cohort, there were six (6) undergraduate and one (1) graduate engineering students, and in the Summer 2015 cohort there were four (4) undergraduate engineering and four (4) second year medical students. While the opportunity was offered, no students repeated the summer program. Based on interest, no graduate students applied in the 2015 cohort, yet opportunity was opened to medical students at the university as well. The main reasons and criteria in selection of those students were that they had undergraduate engineering and science degrees and had entrepreneurial interests in ways to improve health and healthcare. In 2014, the Scholars worked in two groups based on self-selected interests, and in 2015, the Scholars worked in four dyads, each with one undergraduate and one medical student. This pairing aided the engineering students in terminology and understanding in the clinical setting and the medical students in looking at the clinical setting with a different problem-solving “lens”.

An IRB approved survey was used to gain student/Scholar self-reported effect on the their attainment of program and ABET outcomes and objectives, level of interest in bioengineering fields, and likelihood to pursue bioengineering graduate studies or careers. Answers to survey questions were measured with a point system ranging from 1-6 with 1=Strongly Disagree, 2=Disagree, 3=Somewhat Disagree, 4=Somewhat Agree, 5=Agree, 6=Strongly Agree. The same survey was given to the students on the first and last days of the program as pre and post assessments. Average and standard deviations of the data were calculated. A t-test was performed between pre and post results to determine statistically significant differences or trends. Additional feedback was requested from Scholars through comments and discussion and used along with survey results to make program improvements.

RESULTS

Table 1 summarizes the pre and post survey results. The results from 2014, the first year of the program, were previous reported and discussed.[9]

Two areas of the program clearly resonated with Scholars in both 2014 and 2015, the first and second years of the program, respectively. In both cohorts, the Scholars had the largest and significant gains in their ability to understand the patenting process and appreciate the regulatory and reimbursement processes. These two areas were likely new to Scholars in both cohorts. As key elements of the program and Biodesign process, the team was pleased with impact of delivery from the team and guest lecturers and Scholar participation to improve their abilities.

The third area where Scholars improved was in their ability to work with clinicians to define unmet needs. The difference was significant for the 2014 cohort, yet was only a trend for the 2015 cohort. This may be explained by a difference in the background of the Scholars; the 2014 cohort was a composed of nine undergraduate and graduate engineering students, while the 2015 was composed of four undergraduate engineering students and four second year medical students. The medical students were likely more comfortable to be speaking and working with clinicians yet less likely in identifying needs, compared to the engineering students. The addition of three medical students in the 2015 cohorts may also explain why pre and post differences did not exist for Scholar reflection of Engineering Clinic, a Rowan design sequence of courses, and their ability to apply science, math and engineering.

Based on written and verbal feedback about the program for improvement, the area of time and depth of immersion emerged. During the first year of the program, Scholars spent two (2) weeks immersed in the clinical setting and rotating to seven or eight units in that time period. Based on Scholar feedback, one day in each unit, they did not have sufficient time to see a specific case in depth or ask questions to deepen their understanding of the problems. Trading breadth for depth, during the second year of the program, the Scholars remained in a clinical unit for nearly two weeks. After this switch, however, Scholars believed it was too long and they were not getting enough new information after the first week. Thus, the plan for year three became two to three clinical homes that would last 0.5 - 1 week in length as the “sweet spot”. This honing of depth and breadth of specialties would give Scholars enough time to see a case or problem in depth, yet not too long that they became saturated or believed that they had seen what was needed to begin writing needs statements.

Table 1: Items with average score statistically significantly ($p < 0.05$) or a trend^ ($p < 0.1$) increasing on a scale from 1=Strongly Disagree to 6=Strongly Agree

Survey Item	**Pre n = 7 (2014)**	**Post n = 7 (2014)**	**Pre n = 9 (2015)**	**Post n = 9 (2015)**
My Engineering Clinic experience allowed me to connect items from different courses, which I might not have otherwise	4.43 (0.98)	5.43 (0.53)		
I am able to work with clinicians to define unmet needs	4.43 (0.98)	5.58 (0.53)	5.0 (1.0)	5.6 (0.54)^
I am able to translate and commercialize design ideas	3.29 (1.11)	4.57 (0.98)		
I am able to understand and apply medical product development best practice	3.43 (1.62)	4.71 (0.95)^		
I understand the patenting process	2.57 (1.72)	4.57 (0.98)	2.0 (0.71)	4.6 (0.55)
I have an appreciation of the regulatory and reimbursement processes	2.71 (1.89)	5.14 (0.69)	3.0 (1.51)	4.8 (0.44)
I am able to apply knowledge of mathematics, science and engineering			4.6 (1.51)	5.2 (1.30)^
I understand professional and ethical responsibility	4.86 (0.69)	5.71 (0.49)		

CONCLUSIONS

A team of faculty have designed and implemented a novel Clinical Summer Immersion program to improve biomedical engineering education. Participating Scholars, together with engineering and medical faculty, identify clinical needs, gain a deeper understanding of the problems, and further gain exposure in practical issues including intellectual property and regulatory and reimbursement processes. Additionally, the program has allowed for student Scholars to begin translating these needs into solutions through a capstone design process and alongside colleagues in the medical profession. Cross-discipline teamwork is becoming increasingly important as healthcare becomes more complex and greater than the expertise of one subject area. As the program continues, increased interest and activity fostered by industrial partnerships and entrepreneurial activities of the faculty and students is envisioned. Further progress and performance of the program will be measured through pre and post surveys. Projects, invention disclosures and follow-on patents will be tracked to further measure impact.

ACKNOWLEGMENTS

Research reported in this publication supported by NIBIB of the National Institutes of Health under award number R25EB014782 and VentureWell (formerly NCIIA). We are grateful to the business, regulatory, and intellectual property experts, and numerous hospital clinicians, educators and staff for sharing their time and expertise in the summer program.

REFERENCES

[1] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/highlights.pdf (accessed Feb. 2, 2017)

[2] Dym, CL, et al. (2005) "Engineering Design Thinking, Teaching and Learning." J. of Engineering Education, 94(1) p. 103-120

[3] Davis, DC, et al. (2002) "Engineering Design Assessment Processes and Scoring Scales for Program Improvement and Accountability." J. of Engineering Education, 91(2) p. 211-221

[4] Lerner, AL, et al. (2006) "Design in BME: Challenges, Issues, and Opportunities." Annals of Biomedical Engineering, 34(2), p. 200-208

[5] Enderle JD. (1999) "An Overview of the National Science Foundation Program on Senior Design Projects to Aid Persons with Disabilities." Intl J. of Engineering Education, 15(4), p. 288-297

[6] Kotche, D. (2016) "Clinical Immersion Internship Introduces Students to Needs Assessment."ASEE Annual Conf. #15593

[7] Przestrzelski, B, DesJardins, J, Brewer, C, (2016) "Year Two - The DeFINE Program: A Clinical and Technology Transfer Immersion Program for Biomedical Needs Identification and Valuation," ASEE Annual Conf. #17121

[8] Kadlowec J, Merrill T, Hirsh R, Sood S. (2015) "Work-In-Progress: Clinical Immersion and Team-Based Engineering Design," ASEE Annual Conf., Seattle, WA

[9] Sood S, Short M, Hirsh R, Kadlowec J, Merrill T. (2015) "Biodesign Through Clinical Immersion", VentureWell Conf., Washington, DC

[10] Zenios S, Makower J, Yock P. (2010) Biodesign, Cambridge, UK: Cambridge University Press.

[11] https://www.citiprogram.org/index.cfm?pageID=265

[12] Green J, Hirsh R, Jones C, Kadlowec J, Merrill T, Mazurek H, Sood S. (2016) "Biodesign through Clinical Immersion." Cooper University Hospital Research Day poster, design by Alisha Crawford