BIODESIGN THROUGH CLINICAL IMMERSION

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Abstract

The Congressional Budget Office estimates that social security and health care programs made up 9.8% of the GDP in 2014 and projects that total to be 11.2% by 2023 (Congressional Budget Office 2013). Health care must be streamlined to reduce costs while enhancing patient care. Increasing the number of biomedical engineers skilled in translating clinical needs into effective marketable products would help. In the summer of 2014 Rowan University, with National Institute of Health support, developed an intense eight-week summer program for undergraduate and graduate engineers. Key program components included: an overview of the Stanford Biodesign Process, physiology basics, clinical immersion, informatics, intellectual property basics, regulatory basics, business perspectives, and development of best practices. Deliverables included need statements, specifications, and Rowan Engineering Clinic development plans involving identified needs in the areas of implantable defibrillators and biodegradable urological stents. Overall, our program enhanced bioengineering education through a collaboration that included clinical immersion and team-based capstone design projects. Lastly, it provided insight into sustainability and lessons learned for future development.

Introduction

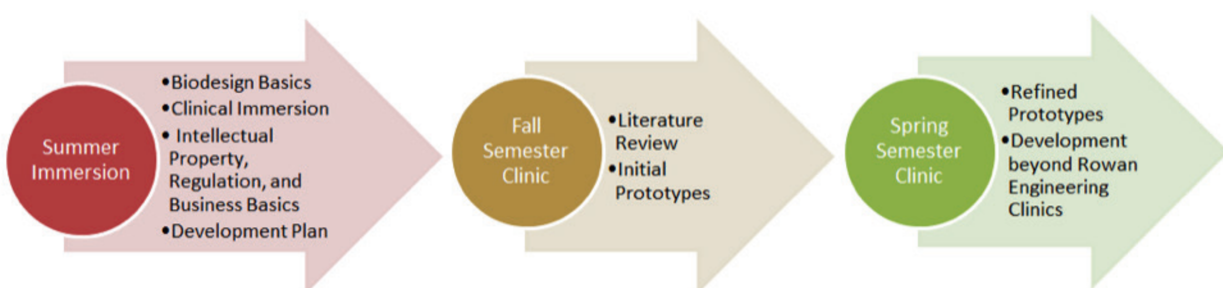

Figure 1: Rowan University Biodesign Through Clinical Immersion and Engineering Clinics

With health care costs in the United States quoted as the highest internationally and rising with our aging population and increased prevalence of chronic disease, there is a clear need for change and innovation to keep up with the increasing demand (Health Care Problems 2015). As designers and solvers of systems, we turn to our engineers-in-training in the hopes of solving the future of health care and medicine.

While there has been a long and successful tradition of teaching engineers theory, the design experiences that are central to engineering education result in deeper understanding of both the key concepts and the practical steps needed to transform those concepts into worthwhile designs (Dym et al. 2005; Davis et al. 2002; Lerner et al. 2006; Kolb 1984). These, as well as practical aspects of eventual commercialization and an understanding of the intricacies of health care, are a necessary part of student training to meet health, medical device, and patient needs while also controlling costs (Enderle 1999). Through real-world experiences, students develop their expertise and ability to use design understanding to develop solutions to engineering design problems (McKenna 2007; Atman 2008; Prince 2004; Roselli and Brophy 2006). Our focus is to improve student learning and design capabilities. We seek to help students create design solutions and develop projects into products. We also seek to offer an example of a model partnership between a university and a clinical collaborator.

Since 1996, Rowan University has excelled at teaching design to undergraduate students through the Engineering Clinics sequence, a unique, multidisciplinary design experience (Chandrupatla et al. 1996). Rowan is one of only two universities in the US where students work on engineering design projects throughout all four years of the curriculum. The Freshman and Sophomore Clinics introduce students to design, reverse engineering, and integrating design projects with written and oral communications (Marchese et al. 1997; Riddell et al. 2008; Dahm et al. 2009; Riddell et al. 2006). This program focuses on building the foundation for the team-based design experiences that occur in the Junior-Senior Engineering Clinics (Kadlowec et al. 2007).

The Junior-Senior Engineering Clinic span the final four semesters of a student's career. The clinics continue multidisciplinary teamwork on semester or year-long projects, which may include both junior and senior students. The 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. The mantra of "design, analyze, build, test, and redesign" is the guiding principle of the Engineering Clinic. Faculty meet regularly with student teams to review progress, teach skills, and guide the design process. Deliverables for each of the projects include a mid-semester design review presentation, a final design presentation, a final design report, and a prototype. Presentations include Introduction/Background, Project Goals and Objectives, Design Development and Calculations, and a Summary of progress and future work. The final reports include the technical design and process as well as a Technological Impact Statement that addresses societal, economic, and environmental impacts, sustainability, manufacturability, and health and safety. This education model has been successful in providing students with real-world, hands-on experiences that result in a portfolio for students to showcase their work to employer and graduate school recruiters. It also helps faculty develop professionally, from developing an experimental apparatus to participating in university outreach through national design competitions.

In addition to its strong engineering focus, Rowan University has recently formed partnerships and mergers with two medical institutions: Cooper University Hospital (2009) and the School of Osteopathic Medicine (2013). These schools qualify Rowan as only one of two universities in the country with both an MD and a DO program. More importantly, Rowan is now a comprehensive university in the areas of basic science research, clinical research, and patient care through affiliations with the Kennedy Health System as well as Cooper University Hospital.

Building on our engineering education success and clinical partnerships, we created a program to improve team-based design education with new projects drawn from unmet clinical needs and a new immersive summer training program using clinical mentorship at the Cooper University Hospital

(Figure 1). Funding for this initiative came from the National Institutes of Health (NIH) and VentureWell, formerly the National Collegiate Inventors & Innovators Alliance (NCIIA).

Overall Program Strategy and Innovation

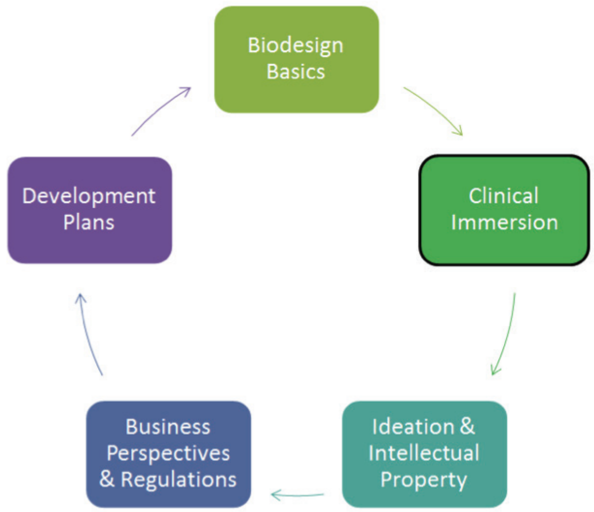

Figure 2: The Rowan University Summer Immersion Program

We organized our overall program with two core aims. First, we sought to develop and deliver an in-depth biomedical engineering summer experience called the Bioengineering Scholars Program involving clinical immersion and practical training on medical technology innovation. Our second aim was to enhance our existing Biomedical Engineering Department and Bioengineering Concentration with new design and development opportunities in our Junior-Senior Engineering Clinics (Figure 2).

We focused on two areas of innovation:

1. We wanted to shift from the prevailing design course paradigm of posing design problems for students to giving students the challenge and responsibility to identify real-world unmet clinical needs.

2. We also wanted to integrate the Stanford Biodesign Process with design project experiences in our Engineering Clinic

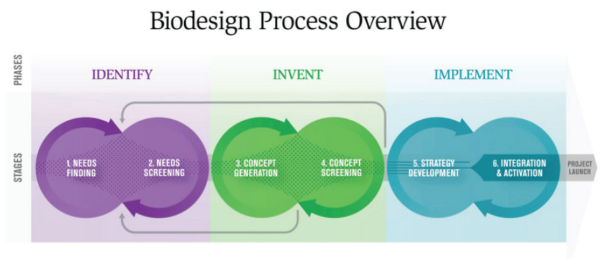

Figure 3: The Biodesign Process[18]

being informed by an immersive clinical experience during the summer at Cooper Medical School at Rowan University (CMSRU) and the Rowan University School of Osteopathic Medicine (SOM). The Stanford Biodesign Process is an experiential method based on three Is: Identify, Invent and Implement (Figure 3). In the immersive summer experience, the students worked primarily in the Identify phase as they completed needs finding, needs filtering, and needs specification statements. To address the Identify and Implement phases, the students prepared Junior-Senior Clinic development plans for the fall and spring semesters. The next section provides a detailed look at our program.

Program Week-by-Week Execution

With our aims in place, identifying the stakeholders and recruiting them was next. Our stakeholders included students, faculty, clinicians, nurses, medical statisticians, business experts, regulatory experts, and intellectual property experts. Students were recruited in the spring semester of 2014 prior to the Bioengineering Scholars Program run in summer 2014. These Scholars were selected through a competitive application process. There were two mechanical engineering (ME) undergraduates, two electrical and computer engineering (ECE) under-graduates, one chemical engineering undergraduate (ChemE), and two graduate students in engineering. Most of the faculty and clinicians were recruited earlier as part of the NIH grant application process, however several additional experts in business, regulatory, and intellectual property were recruited through our networks. Clinical specialties included critical care, obstetrics and gynecology, cardiology, anesthesiology, trauma, nephrology, and informatics. Non-clinical experts included a retired FDA official, an intellectual property attorney with medtech experience, a medtech entrepreneur developing innovative solutions for laparoscopic hysterectomy, and a medtech engineer with over 20 years of experience at large and medium sized firms.

With our team in place, we organized an eight-week multidisciplinary summer experience that involved three parts: 1) learning about the basics of physiology and medtech innovation, 2) identifying clinical problems and formulating need statements, and 3) taking these needs closer to solutions and translation to actual products. Table 1 below summarizes the 2014 Rowan Bioengineering Scholars Program:

WEEK	TOPIC	DELIVERABLE
1	Overview of program and basic physiology	Real-world med-tech 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

Table 1. Summer 2014 Rowan Bioengineering Scholars Program

Week 1: Stanford Biodesign and Physiology Basics

The Stanford Biodesign Process is broken into three parts: identification, invention, and implementation. Each scholar was provided with a copy of *Design in Biomedical Engineering* by Zenios, Makower, and Yock (2010). In week one, we focused primarily on identification, namely needs finding and needs screening. First, we identified scholar interests and grouped teams so that they came close to sharing a common strategic focus. This strategic focus was also based on strengths and weaknesses in the core engineering areas: electrical, chemical, and mechanical engineering. We wanted them to envision being a part of a small start-up company made up of employees with common interests. Next, we discussed best practices for observation and problem identification in the clinical setting. We wanted to make sure that the time spent in clinical immersion was effective for identifying patient care problems. Recognizing that problem statements represent an initial step in the medtech innovation process, need statement generation best practices were also covered. Need statements represent links between observed problems and potential solutions. They help narrow the gap between the two. To create effective need statements we highlighted two pitfalls: 1) embedding a preconceived solution in the need statement (e.g., stating a stent is necessary) and 2) poorly defining the scope of the need (e.g., saying that there is need to improve heart disease treatment or a subset of a disease that affects few patients).

Since a majority of the engineering students did not have physiology training, four three-hour sections were offered covering gastrointestinal, respiratory, endocrine, and cardiovascular physiology. Our intent was to provide the students with awareness, some understanding, and the resources to discuss and research common patient diseases and disorders they might come across during clinical immersion. Students were also assigned Responsible Conduct of Research Training to be completed within the first month of the program. To close out the week and to build excitement for innovation and not lose sight of the big picture – translating solutions to the bedside – we asked each scholar to explore a database of Stanford Biodesign fellow and student companies. We asked each scholar to select a company and summarize their product and their stage of development.

Weeks 2-3: Clinical Immersion

After focusing heavily on the first 'I' in the process (Identify), the Scholars began their journey into the clinical settings in order to explore the health care system of our partner hospital and speak with clinicians to discover and determine needs. After a brief orientation as hospital volunteers, the Scholars donned scrubs and became part of the health care system, watching and discovering, with a first stop in surgery.

Throughout the two weeks, they shadowed on rounds with patients on the medical and surgical floors and in Intensive Care Units, participated in discussions with doctors, nurses, technicians, hospital staff, secretaries, and patients, and attended Grand Rounds. The Scholars had first-time experiences in surgery and trauma, and even saw the birth of a newborn. Clinicians were impressed with the Scholars' level of interest in what was happening around them and the different perspectives from which they looked at medicine and the health care system. The clinicians and specialists were specifically selected based on their interest in the program and working with students in this format, which was to be similar to working with medical students on rotations in a CMSRU program called "Week on Ward" or WOW. A key difference between Immersion Scholars and WOW medical students was that while WOW students were learning standard patient treatment and care, Scholars were looking for problems to solve.

Throughout these observations, Scholars were asked to define the complete care cycle and take into account three observational perspectives: the patient, the provider, and the other health care stakeholders such as regulators, insurers, and administrators. Stressed problem areas included pain, death, and stress (patient), risk, malfunction, uncertainty, dogma (provider), and finally cost and inefficiency (others). Each Scholar maintained an "innovation notebook" to ensure that observations were accurately captured (Zenios, Makower, and Yock 2010). For a few hours at the end of each week, both engineering and clinical faculty met with the Scholars to discuss their observations. Through discussions, debriefing sessions, and written assignments, the faculty team facilitated as students identified problems and defined needs in preparation for writing needs statements and brainstorming potential solutions.

Week 4: Concept Generation and Intellectual Property Basics

Week four was a transition week. In this week, Scholars began to translate problems observed during immersion into need statements that did not embed solutions and did not have improper scopes (too big or too small). At this stage, some Scholars felt overwhelmed by dozens of observed problems and the pending needs statement deliverable. To lighten the mood and allow exploration of creative ideas, we focused on the second "I" in the Stanford Biodesign Process: Invention. Since the origin of inventing is idea creation or "ideation," we provided best practices for group and individual creative thinking. Pulling from the Biodesign text and Roger von Oech's book *A Whack on the Side of the Head: How You Can Be More Creative*, we tried to create a fertile environment to forge solutions to the observed unmet clinical needs (Zenios, Makower, and Yock 2010; von Oech 1990).

Translation also depends on converting these potential solutions into actual products with intellectual property protection. To help the students appreciate this practical aspect of medtech innovation, an intellectual property lawyer with medtech experience delivered overview lectures, including: the anatomy of a patent, determining patentability, licensing, patent ownership, overall patent strategy, and intellectual property costs. Numerous case studies and roundtable discussions were used to enhance the learning environment.

Week 5: Regulatory and Business Perspectives

In week five, the Scholars dove deeper into the practical ideas of translation: regulatory basics and business perspectives. A retired FDA official delivered lectures on core regulatory concepts, providing an introduction to this crucial and sometimes overlooked challenge. The lectures included the overall mission and responsibility of the FDA, integrating design controls to improve regulatory outcomes, and the basics behind materials selection, biocompatibility, and product verification and validation. Business perspectives were broken into two parts: large business and small business. An experienced medtech engineer and manager led the large business discussions on identifying customer needs, drivers and barriers to new product development, and product descriptions versus specifications. A local entrepreneur working on woman's health technology led the discussion from a small business perspective, exploring the challenge of raising funds for R&D, project execution, and adapting to inherent development changes along the way.

Week 6: Needs Filtering and More Business Perspectives

While another practical business perspective of US medical device reimbursement was covered in week six, the primary focus was on winnowing or filtering the initial unmet clinical needs into a preferred set worth developing. Typical filtering involved reducing a list of ten unmet clinical needs down to three unmet clinical needs. Initial needs spanned all the clinical immersion experiences listed previously: trauma, critical care, urology, obstetrics and gynecology, cardiology, nephrology, informatics, and anesthesiology. The primary criteria for filtering included market size, patient impact, provider impact, feasibility, interest, and a revisit of focused clinical physiology from the perspective of a biomedical engineer, a medical student instructor from SOM.

Week 7-8: Continued Needs Filtering and Final Deliverables

To further narrow students' options to three to four needs with potential solutions, week seven focused on areas of clinical need, cost effectiveness, and feasibility for completion in the Engineering Clinics during the academic year. Scholars met with professors from the physiology department, as well a physician from the family medicine department at SOM, to gauge potential solutions from the basic science and clinical perspectives. Student discussion was facilitated by the medical student instructor introduced to the program in week six. Once needs and potential solutions were finalized, we spent the remainder of the week on devising prototypes, considering the necessary materials, and planning for the academic year in the Engineering Clinic. During the latter half of week seven and into week eight, the teams of Scholars drafted their project posters and reflections for presentation at the end of program symposium open to all relevant faculty and staff.

Program Outcomes

Feedback and assessments were given by the lead faculty for the immersion on the Scholars' deliverables. There were two primary deliverables, each of which were completed in pairs or solo for each of four different needs. First, the Scholars created a need specification statement 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 the 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 Junior-Senior Engineering Clinic in the academic year. Two Scholars, who worked on the needs specifications and development plans over the summer, continued on the project during the academic year and served as the student team leads. 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 the NIH and VentureWell funds), which is similar to the structure of other Junior-Senior Clinic projects. The first project involved a novel implantable cardiac defibrillator with a remote notification system to alert medical personnel of important device events. The second involved developing biodegradable catheters using silk to avoid additional costly removal procedures for urological catheters. Silk was chosen for its naturally biodegradable and biocompatible material properties; it can be engineered to be safely implanted and will dissolve. In both cases, these projects are continuing in the spring semester as well.

We assessed the programs effect on the students' attainment of both program and ABET outcomes and objectives, level of interest in bioengineering fields, and likelihood to pursue bioengineering graduate studies or careers using an IRB-approved survey study. 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. Points were averaged among the students and compared in pre and post surveys given to students on the first and last day of the program. We found statistically significant increases (TTEST, $p<.05$) in the areas listed in Table 2. Additionally, we asked for informal feedback during the program to help us improve along the way and in future offerings.

SURVEY ITEM	PRE	POST
My Clinic experience allowed me to connect items from different courses, which I might not have otherwise	4.43	5.43
I am able to work with clinicians to define unmet needs	4.43	5.58
I am able to translate and commercialize design ideas	3.29	4.57
I understand the patenting process	3.43	4.71
I have an appreciation of the regulatory and reimbursement process	2.71	5.14
I understand professional and ethical responsibility	4.86	5.71

Table 2. Items with average score statistically significantly ($p < 0.05$) increasing on a scale from 1=Strongly Disagree to 6=Strongly Agree

As Table 2 demonstrates, students became more confident and comfortable working with clinicians to identify issues and connecting ideas from different professions and prior experiences in the Engineering Clinic. To progress in the clinical field, the professional divide between engineers and clinicians must be overcome. This increase shows the success of this vital aspect of the program and the Biodesign process. Through classroom instruction in physiology, followed by clinical shadowing and further physiological studies, students gained a much greater understanding of the clinical profession and environment to the point of finding productive common ground. Further, students believed they made large increases related to the medical device design process, specifically: ability to translate and commercialize design ideas, understand and apply medical product development best practices, understand the patenting process, and appreciate the regulatory and reimbursement process. The didactic coursework and guest speakers, in conjunction with the immediate application in the context of medicine and medtech devices, is an effective way to increase the understanding of these processes and bring together new areas and concepts for students.

Going Forward: Future Improvements

The first year of immersion was a learning experience for everyone involved. As discussed, student Scholars benefitted greatly from an immersive experience working with clinicians to determine needs and learn the Stanford Biodesign Process as the basis for their design projects. This process will also serve them well in other future design endeavors. From the faculty perspective and based on student feedback, we believe some adjustments to the program would benefit both the Scholars and their teammates who join the Junior-Senior Engineering Clinics, as well as streamline the process for the faculty team.

One positive change suggested by both students and faculty was to increase the immersion time and cover relevant physiology during and after. The idea is to allow student Scholars an iterative cycle with more time to take in a health care problem, reflect upon it, follow up with more questions, and repeat the process as a need is developed, all while learning physiology in a more case-based approach in areas that are relevant to the immersion. The students and faculty also discussed the idea that some of the intellectual property, business, and prototyping concepts, while useful, perhaps would have benefited the teams even more if they had been discussed further along in the design process. In the future having students do just-in-time learning activities, such as online medical physiology training, alongside their projects during the academic year may be an approach that would improve project development for the Scholars and their teammates, who were not participants in the summer program.

Finally, the lead faculty noted other ways to improve the summer program for the Scholars, while streamlining, by increasing team-teaching. Now that we have our first group of Scholars who have completed the program, we plan to recruit at least one to return as a peer mentor and assist with instruction and discussions. We plan to have new faculty in the recently established Biomedical Engineering Department and other engineering faculty working in bioengineering areas join us in delivery of experimentation and techniques in their areas of expertise to broaden student's knowledge in different areas, particularly those needed for their projects.

Conclusion

Looking back, in addition to emphasizing design over theory and analysis, the summer clinical immersion experience exposed the students to a full gamut of health care delivery realities. The Scholars' hands-on training was analogous to that of medical students, interns, and residents who participate in rounds and shadow, attend lectures, and speak to all manner of people from patients to staff to nurses and doctors. They learned to discover, through query and engagement, problems in need of solutions by finding it in the voice of the people who deliver and receive the care and design solutions to improve health care.

Participating students were from varied engineering disciplines with little to no prior exposure to biological or clinical concepts.

Through mentorship and immersion in the clinical environment, as well as simultaneously participating in biomedical design process coursework, students were able to identify needs and apply product development, patent, and regulatory processes that provide the foundation for the design experience to occur in the Junior and Senior years of the Engineering Clinic. The three potential projects that resulted from this experience included innovations in cardiac defibrillator devices, urological materials, and software for monitoring vitals and systemic infection criteria. Each project and potential solution demonstrates an understanding of health systems, human systems, and the design process gained throughout the immersion program.

Finally, this program serves as a model for this year's upcoming biodesign experience. With this first round complete, we can now begin our recruitment process earlier and more effectively. We intend to target more engineers with a medical technology interest, in addition to second year medical students, to allow for a more comprehensive collaborative learning experience in summer 2015.

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