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# Bridging Courses: Unmet Clinical Needs to Capstone Design (Work in Progress)

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# Work in Progress: Bridging Courses, Unmet Clinical Needs to Capstone Design

## Introduction

Often in the academic arena, biomedical engineering (BME) students identify unmet needs in a course and then do not have an avenue to pursue those ideas into a design-based course. Through funding from an NIH R25 Educational Grant the BME Department at the University of Delaware (UD) is building a bridge between two courses, Clinical Immersion for Engineers (BMEG350) and Senior Design (BMEG450), to translate umnet clinical needs into design projects. This paper discusses the two courses and how the unmet needs are bridged into Senior Design.

## Course Descriptions

Clinical Immersion for Engineers (BMEG350) is offered over UD's 5-week winter session (January through the first week of February). In the course, students are paired with clinicians at local clinical sites, including hospitals, physical therapy clinics, and with prosthetic/orthotic practitioners. Through the 5-week term the students spend 25 hours a week in the clinical setting shadowing the clinicians (going on rounds, attending surgeries, etc.) and identifying unmet clinical needs. The students have weekly group discussions with the course instructor, homework assignments, and maintain a blog to document their immersion experience and an inventory of identified unmet needs. At the end of the term there is a poster session where the students present a proposed solution to one of the unmet needs. The enrollment for Clinical Immersion is 15 - 20 students placed at 6 - 7 clinical sites. The clinical sites have specialty areas for immersion, e.g. cardiology, general surgery, sports medicine, genetics, stroke rehabilitation, and otolaryngology, and each site and specialty area may host more than one student.

**Table 1.** Senior Design Timeline and Phases

| Timeline | Project Phases |
|---|---|
| Weeks 1-2 | Phase 1: Introduction & Design Metrics |
| Weeks 2-5 | Phase 2: Concept Generation & Selection |
| Weeks 6-9 | Phase 3: Final Design, Prototype & Project Budget |
| Midterm | Oral Presentation, Outside Reviews |
| Weeks 10-15 | Phase 4: Design Validation, Conclusion & Path Forward |
| Final | Oral Presentation, Outside Reviews & Poster Session |

*Falls in the middle of Phase 3, closer to week 7-8

Senior Design (BMEG450), a capstone course, is an intensive 6-credit, one semester, team-based project driven course, which requires strong teamwork and application of engineering, science and design principles to solve a sponsor driven problem. Traditionally, industrial partners and university researchers have sponsored the design projects. The sponsors provide a scope of work statement, which is an overview of the project need. The sponsors also pay a sponsorship fee, which covers overhead (support staff, maintenance of design space, general supplies, etc.) and the team's prototyping fees. Senior Design is broken down into four design phases with deliverables throughout the course of the semester (Table 1). At the end of the course the teams give an oral and poster presentation to an external review panel and present the sponsors with a final report and working prototype. During Senior Design, the BME students have the opportunity to work on BME-only teams or on interdisciplinary engineering teams with civil &

environment (CIEG), computer & electrical (ECE), and mechanical engineering (ME); teams range in size from 3-4 students. The composition of the teams depends of the project need. The enrollment for Senior Design during 2015 was 90 students total (50 BME, 5 CIEG, 5 ECE, and 30 ME students).

Methodology

When Clinical Immersion for Engineers was established there was no clear mechanism to bring the unmet clinical needs that were identified into Senior Design. During Winter 2014 two of the clinical groups expressed interest in working with a design team to develop a working prototype of the unmet need. The groups were the Cardiac Center at Nemours AI DuPont Hospital for Children and a general surgeon from the Helen F. Graham Cancer Center. Both entities had their own funding sources to support the senior design teams. In the 2014 offering of Senior Design these two design projects were part of senior design, "3D Models of Congenital Heart Defects" and "Endoscopic Surgical Tools". Both projects were very successful; one project was a BME only team and the other an interdisciplinary team (2 BMEs and 2 MEs). Other clinicians are interested in participating in Senior Design but the lack of funding to cover the fees needed to support a design project. The success of these initial two project and the funding provided through the NIH R25 Educational Grant facilitated bring three clinical design projects in the Fall 2015 offering of Senior Design.

The target for year one of the NIH R25 funding was to bring two to four clinical projects into Senior Design from Clinical Immersion for Engineers. In year one, 2015, three design projects came out the relationships established through Clinical Immersion (Table 2). These projects were a part of the overall Senior Design course, the student time requirements were the same as the non-clinical projects. To bring these projects into Senior Design the inventory of unmet needs was evaluated for their feasibility to fit into Senior Design. The unmet needs and the senior design process were discussed with the respective clinicians. Through the conversations the interest to sponsor a project was gauged and the expectation of the sponsor were outlines (weekly/bi-weekly meetings, shadowing in the clinical setting). One of the challenges is the sustainability of clinical-based projects. The hope is that the NIH R25 funding will allow us to establish and build the relationships with clinical collaborators. We are looking for other funding sources (university education-based grants, other government agencies). Additionally, the clinicians have indicated that once we show success that their institutions might have funds to help support the design projects.

**Table 2.** 2015 Clinical Projects (Year One NIH R25)

| **Clinical Specialty** | **Project Focus** |
|---|---|
| Otolaryngology | Removal of Cholesteatoma from the Middle Ear |
| Anesthesiology & Pharmacy | Narcotic Identification and Elimination of Drug Diversion |
| Sports Medicine | Redesign Operating Room Floor Mats to Reduce Water Run Off |

Senior Design Project Assignment

On the first day of Senior Design the students are given an overview of the course (four phase design process, deliverables, grading structure, and resources) and the project ideas are introduced. During the introduction of the project ideas the team compositions are also presented (number of BME, ECE, CIEG, and ME students needed for each project). As stated earlier the

composition of disciplines is based on the project need. The students have an opportunity to meet the project sponsors at an event called Sponsor Night. The students rank their top ten project choices as well as provide a justification for being selected for the projects. From the preference ranking and justifications the students are divided into teams for each project. In the 2015 offering of Senior Design the BME students could bid to work on 20 of the 22 projects. Of the 20 projects the number of BME students per team ranged from 1-4 students, with 4 being the maximum number of students assigned to a team. The BME-based companies that sponsored projects are Terumo, IPO, DePuy-Synthes SimuCare, West Pharmaceuticals, LiteCure, Seimens Healthcare Diagnostics, and several smaller companies. BME students are assigned to BME based projects unless the student provides a very compelling reason for placement on a non-BME based project.

The student composition of the teams for the clinical projects was BME-only teams with 3-4 students per team. The clinically sponsored projects were incorporated in with the rest of the projects in Senior Design (22 projects in 2015), having the same time requirements and following the same course schedule as the rest of the Senior Design course. During Senior Design the students and clinicians have weekly or bi-weekly meeting (phone call or in person) to identify design constraints of the projects, discuss prior art, preliminary design or research concepts, and design iterations. The students shadow the clinician in their respective clinical setting, to gain a better understanding of the complexity of the environment and interview end users.

Pre and post-surveys were administered to the Senior Design students. The pre-surveys were sent to the 11 students on the clinical projects and the post surveys were sent to all 50 BME students in Senior Design. All 11 students on the clinical projects completed the pre-survey, but only 20% (10 of the 50, 3 from clinical projects) completed the post-survey. The results from the pre-survey illustrate the student's interest in working in a clinical setting and on projects that are directly applicable to the biomedical field. Several of the students were also drawn to the projects due to direct application of their academic strengths and laboratory skills. The results from the post-survey are harder to interpret due to the low response rate. Overall, senior design (both industry and clinical projects) is a well-received course where the students learn valuable skills. However, there are areas that BME students feel that they are lacking the necessary skills to excel (CAD, machining, engineering design) and the pre-survey also called out these skills. To address this shortcoming, we are teaching an in-depth engineering design course at the junior level. The course includes CAD, arduino, machine shop training, and a sponsor driven project.

Assessment/Outcomes

All of three of the clinical projects in the 2015 offering of Senior Design course were great learning opportunities for the students and the faculty and also presented some challenges.

*Challenge 1: Materials Transfer for Human Tissue*

The first challenge was faced early in the semester and almost resulted in a change of scope for the Otolaryngology sponsored project. The project require work with de-identified human tissue. Before the samples could be sent to UD a Materials Transfer Agreement (MTA) needed to be set-up between the hospital and the university. Although this is a standard agreement the time to execute was not anticipated (almost 8 weeks). Due to the lag time for the project to get started

the students and sponsor agreed, that if needed, the scope of the project would shift to an adaptation of a surgical tool. We were able to receive the tissue in time for the students to work on the original project idea and the students worked tirelessly over the last six weeks of the semester to generate meaningful results.

*Challenge 2: Design-based Projects vs. Experimental-based Projects*
In Senior Design, as well as other engineering design courses at the university, we use a Design Manifesto to guide the students through the four-phase design process. The manifesto outlines the deliverables for each of the phases and the phase subcomponents. Two of the clinical projects, Otolaryngology and Anesthesiology & Pharmacy, were more experimental-focused project than design focused project. By experimental focused project we mean the project required more experimental design and analysis rather than the building of a prototype. To address a new design manifesto (Research Manifesto) was written to reflect procedure for experimental-based approach verses design-based approach. The honors students on these projects, five of the eight students, were tasked with writing the new research manifesto as their honor component to Senior Design. The honors component needs to be value adding but not critical path.

*Challenge 3: Sponsor Meeting with Teams*
After mid-semester two of the clinicians, Sports Medicine and Otolaryngology, were not as accessible to the students. This impacted the pace of the projects and the outcome of the Sports Medicine Project. For the success of the project it is imperative that the clinician remains engaged and are able to to make time to meet with the design teams. In the future, we plan to make these expectations more explicit (written) to both the students and the sponsors. We also plan to coach the students to ensure that meetings with sponsors are focused and efficient.

Two of the clinical immersion projects (Otolaryngology and Anesthesiology & Pharmacy) are ongoing as independent studies projects through spring semester. The Otolaryngology project has gained the interest of two faculty members in BME to continue the research in the development of an animal model for pre-clinical trials and the development of targeting molecules to label the cholesteatoma (over growth of keratinized tissue in the middle ear). The team has also submitted abstracts to several design competitions and are working with the project sponsors on a publication. The Anesthesiology & Pharmacy project is working with their sponsors to explore commercialization pathways for technology and have applied for start-up funding through a university entrepreneurship program.

## Conclusion
The success of the clinical projects from 2014 Senior Design and the NIH R25 funding have provided a bridge to bring the unmet needs identified during Clinical Immersion for Engineering into Senior Design. In 2015 Senior Design three unmet needs from Clinical Immersion were brought into Senior Design. The teams on these projects were BME students only and this was based on the needs of the projects. One of the projects (Sports Medicine) culminated in a prototype. The other two projects (Otolaryngology and Anesthesiology & Pharmacy) were experimental-based projects and concluded in strong preliminary findings and a research plan that was be carried out the next semester.