AC 2008-757: INTEGRATING EXTERNAL MENTORS INTO BME SENIOR DESIGN

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Introduction

To build strong independent design skills, our department exposes students to more and more open-ended projects through our curriculum. The culminating experience is a two-semester, team-based senior capstone project, mentored by external biomedical experts and advised by faculty within the department. The single most important goal of the capstone experience is for students to function as biomedical engineers in a realistic medical setting. The unique aspects of our approach are: 1) the relationship between the external mentor and students and 2) the process of identifying and defining the capstone problem. Rather than beginning the capstone with a pre-defined problem, the students work with the mentor in his or her medical setting (e.g., operating room, clinic) to identify several relevant, biomedical challenges. The students then work with input from the mentor to choose the problem that is best suited for the design project. The students are responsible for framing this medical problem as an engineering problem. A great deal of emphasis is therefore placed on the problem identification and definition as critical steps that occur before the design process begins. In the remainder of the capstone the external mentor serves as a member of the design team and is a frequent contributor to the design process. Here we report our initial experiences on the important role external mentors play in senior capstone. The course structure and roles of the members of the design team are outlined, followed by an assessment of our model.

Course Structure

Overview

To prepare for senior design all juniors are required to take a half semester course that covers device benchmarking, the FDA, patents and intellectual property, teamwork, environmental impact, and formal decision making. In the senior design sequence the focus is on the design process in the first semester a functional deliverable in the second semester. As the content and sequence of our capstone experience is similar to other programs, this paper will focus on the impact of external mentors on our design capstone. Although the design process is presented below in a linear fashion, students are expected to return to different stages of the design process based upon feedback from their faculty advisor and external mentor.

Fall Semester Senior Year

In the fall semester, seniors interact regularly with an external mentor to identify a medically relevant problem, gather relevant background information, develop specifications, generate a list of alternative solutions, and finally select and justify a solution.

<u>*Problem Identification and Definition*</u>

The process of problem identification begins early in the semester at a meeting between the students and external mentor. After this initial meeting, the students will typically spend time with the mentor in his or her professional setting (e.g., clinic, operating room) observing and gaining exposure to the environment. These meetings and experiences allow the students to both ask the mentor to list and explain significant problems he or she regularly encounters as well as identify some new problems on their own. Throughout this process, the students meet with their faculty advisor to gain an additional perspective on the possible design problems. The students are ultimately responsible for selecting the design problem with input from the team's external mentor and faculty advisor.

Following identification of a problem, students are required to write a concise written problem statement with no mention or implication of a solution. Although students share their problem statement with their advisor and mentor, and will receive feedback, it is up to the students to refine the statement as the project progresses.

Users and Device Specifications

Based upon the problem definition, the students develop a list of potential users and specifications that any proposed solution must satisfy. Again, the mentor may suggest clinical users and functions the device should perform to solve the problem. The students, however, are expected to expand the list of users to encompass anyone who may come into contact with the final device throughout its lifetime. Furthermore, the students must translate the desired functions of the mentor into testable engineering specifications.

Alternative Solutions

Given the specifications, student teams brainstorm diverse and distinct solutions that meet all or most of the specifications. The mentor is often an excellent resource as they can suggest sources of relevant background information and explain any existing solutions to the proposed problem. The team performs an analysis of the alternative solutions using a decision matrix and presents the top three or four solutions to their faculty advisor and external mentor.

Proposed Solution

In the generation and selection of candidate solutions, students typically focus on the technical aspects of their alternative solutions. In selecting a single solution, students must consult their external mentor. The goal is to include any important design specifications that may have been missed and update the weights in the decision matrix. Using the updated decision matrix, students select a design that will best solve the problem outlined in the problem definition by meeting specifications.

Feasibility Tests

Once a solution has been selected, students must demonstrate that their chosen solution is technically feasible. In the Fall semester students must identify the technical hurdles that must be overcome and design tests to demonstrate to the advisor and mentor that the proposed solution is possible and will satisfy the specifications. Often in developing feasibility tests, the mentors help students identify flaws in the proposed solution. In these cases, the list of alternative solutions must be revisited. For the Fall semester, students are encouraged to begin with simple proof-of-concept tests that may be conducted at our institution.

Project Proposal

Throughout the semester students are required to communicate their progress in formal meetings, written assignments, weekly memos and a mid-semester oral presentation as well as document their work in an electronic design history file. The written assignments parallel the design process outlined above and become components of a project proposal. In addition to the technical information presented, the project proposal must also include a budget and Gantt chart for the Spring semester. Although the external mentors will review the proposal, and may offer feedback, they do not assign a grade.

Spring Semester Senior Year

In the spring semester, students focus on the steps required to create a functional deliverable, including feasibility testing, the creation of a prototype and construction of a working device. Communication with the mentor is again maintained throughout the semester by weekly memos and meetings, as well as written and oral presentations.

Feasibility Tests

Students are expected to continue testing the feasibility of their chosen solution. Although some feasibility tests may be conducted at our institution, it is often the case that some tests require clinical observations or measurements. The mentor therefore becomes critical for many groups who must show usability and compatibility in a medical environment.

Prototyping

Early in the Spring semester, students are expected to create a prototype of their proposed solution. The goal is to demonstrate to the external mentor how the final functional deliverable will operate. The external mentor is expected to give feedback which should be incorporated into future prototypes and the final functional deliverable.

Device Benchmarking

The students must develop a benchmarking plan to assess whether or not their final device meets each specification. Similar to the feasibility testing, the external mentors may provide the appropriate medical environment in which to perform the final benchmarking.

Functional Deliverable

All groups are expected to create a functional deliverable that solves the problem as stated in the problem description by meeting all specifications. Results from the benchmarking tests are used to assess whether the device passes or fails each specification. At the conclusion of the semester, students present the final functional deliverable to the external mentor. The external mentor may provide feedback but does not assign a grade.

Final Report and Exposition

A final design report is required of each group and is composed of all technical information leading to the functional deliverable. In addition to the technical information presented, the final proposal must also include a non-disclosure agreement, an assessment of marketability, an FDA approval plan, environmental impact statement and assessment of liability. The level of detail in each of the non-technical sections varies based upon the interests of the external mentor and students. Although external mentors do not assign a grade, they are required to read the final report and give feedback to the faculty.

In addition to the design report, students must demonstrate the functionality of their device in a public exposition. External mentors are encouraged to attend the exposition.

The Design Team

While the success of each design project requires effective contributions from all participants, the roles of the participants are different. The list below is distributed on the first day of class to every member of the design team. All members are required to initial next to their corresponding section. In this way, the list functions as a team contract to be followed throughout the year.

Students

- Ultimately responsible for identifying the problem of interest, proposing and evaluating potential solutions, selecting the optimal solution, producing a functional prototype, managing budgets and evaluating all areas of biomedical design relevant to the project.
- Prepare and distribute weekly project update memos
- Prepare for and run all meetings with advisors and mentors
- Prepare all project documentation according to course guidelines
- Proactively initiate communications/meetings with advisors, mentors and others (e.g., technical staff, other engineering faculty) who may be of value to the project.
- Satisfy all course requirements and assignments.
- Critically evaluate all feedback from advisor, mentor and others consulted about the project and determine the appropriate course of action in response to project feedback.
- Keep communication with the advisor and mentor to an appropriate amount such that mentors are not inundated with inquiries from multiple team members at once.
- Exhibit professional behavior in interactions with other team members, the advisor, the mentor, and the course coordinator.
- Document all phases of the design project in the electronic Design History File.
- Utilize effective teamwork and team based skills in accomplishing project goals.
- Meet all project deadlines.

Advisor

- Meet weekly for up to one hour with design team during scheduled lab time
- Provide effective and constructive technical advice to design teams in order to assist them in navigating their way through the process.
- Provide timely feedback on written assignments when appropriate.
- Provide prompt responses to out of meeting questions from teams.

- Maintain communication with the external mentor to monitor project process and effectiveness of mentor process.
- Direct teams to other experts at Bucknell who may be of value to a project especially if a project is outside the advisor's technical expertise.
- Evaluate technical progress and professional behavior of team members.
- Provide analysis and associated grading to the course coordinator.
- While it is the responsibility of the advisor to provide technical advice and suggestions, it is not his/her responsibility to make decisions for the team, provide answers to problems that a team is expected to solve, or tell a team when they have done enough work.

Mentor(s)

- Provide biomedical clinical and/or technical advice to a senior design team.
- Provide an opportunity for teams to gain experience in a clinical or laboratory setting.
- Commit to the project for nine (9) months.
- Commit to meeting with the design team before the second week of classes. (This is mandatory for all participants in the project)
- Communicate any concerns about interacting with the team to the advisor.
- Provide prompt feedback to student questions in order to avoid long pauses in the process.
- At a minimum, meet in person with the teams at least three times in the fall semester and three times in the spring semester.
- Participate in periodic project evaluation as requested by the instructor. Input from the external mentor will be extremely valuable in assessing student projects.
- Commit to a final project meeting at the conclusion of the project.
- Provide feedback to the faculty at the end of the project with regards to the mentor process.
- May utilize a co-mentor model and share the duties with a colleague.
- Be aware of student deadlines and be considerate of how the mentoring process affects meeting those deadlines.
- Avoid dictating the exact project direction or indicating which solution teams should pursue. These actions would inherently circumvent the educational process.

Course Coordinator

- Create all required course documents including syllabi and assignments.
- Review all appropriate student work with regards to university writing requirements.
- Maintain periodic communication with external mentors and faculty advisors.
- Provide advice and guidance to student teams with regards to the design process and project management.
- Responsible for all final grades based upon input from project advisors.
- Provide instruction to students on the design process and all associated professional skills.

- Monitor the overall budget for the course.
- Act as resource for teams in areas of teamwork and conflict management.
- Have ultimate responsibility for establishing due dates for assignments.

As the faculty advisor is paired with a design team before the direction of the project is known, it is often the case that students will solicit input from an external consultant. Most typically a consultant is another faculty member at our institution, an additional external mentor or an industry contact. The role of the consultant varies based upon the discretion of the students, but has ranged from a single phone call to inclusion in the design team. To further enhance the students' access to technical, one hour is scheduled each week during which students may request a meeting with any member of our department.

Course Logistics

Finding Mentors

Finding and recruiting external mentors who will fulfill the duties above can be challenging. Although all members of the faculty are involved in the recruiting process, the department chair typically initiates the process by organizing a design exposition at our closest medical center in June. At the exposition, faculty demonstrate projects from the previous year and are available to answer questions about the role of the mentor. Our program has also created a flier and presentation that briefly explain the process, expectations and benefits of being a mentor.

Creating the Design Team

Each design team is created by a double blind process. External mentors are selected and required to submit a short abstract of their area of expertise. Specific problems are not included in the abstract. On the first day of class, students and faculty are assigned an ID number and then independently rank the projects. The course coordinator assigns teams based upon these rankings but only knowing the ID numbers. After the assignment is complete, the ID numbers are mapped back to the individual faculty advisors and students.

Institutional IP Agreement

Due to the potential for liability, our institution has historically not retained the intellectual property generated by senior design projects. A legal agreement has been developed between our institution and the nearest medical facility such that any intellectual property generated is owned by the medical facility. In the agreement, it is made clear that the final functional deliverable is not to be used outside of a laboratory setting and by no means may be used in a clinical setting of any type. An agreement with mentors at other institutions is handled on a case-by-case basis. Students, not being employees of our institution, are asked to waive their rights to IP in a separate document. Although it has not happened, students would be reassign to independent design project if they refused to sign away their IP rights.

Design Budgets
Design teams are able to request the use of departmental resources through the approval of the faculty advisor. In addition, the external mentor may donate materials or share relevant medical equipment. To cover any additional expenses, all groups receive a fixed budget for the duration of the project. All items purchased using the budget must be approved by the faculty advisor.

Student Travel Policies
Students are required to travel off campus to meetings with their clinical mentors. Two mechanisms are available for student transportation. First, students may rent a car from the university. Mileage is charged to their design budget. Driving a university car requires completion of the university driving course. Second, students may use their own vehicle and have the option to reimburse their mileage using their budget.

Mapping to ABET

The typical content of most senior design courses satisfy a large number of ABET criteria. The focus below is upon four criteria that benefit the most from the external mentor model.

Life Long Learning
Regular professional interactions with a person who is not a peer, professor or engineer, and who will not be assigning an explicit grade, is a unique challenge for most students. The nature of the projects also requires every team to consider a wide range of sociopolitical issues and learn technical skills that are not explicitly part of the curriculum.

Communication
Unlike a traditional course, students are no longer communicating with a single professor. The course coordinator, faculty advisor and external mentor review all written work and a mixed audience is typically present at meetings and oral presentations. Students must therefore learn to effectively communicate ideas to multiple audiences, sometimes in the same communication. The design proposal and final design report may also be evaluated by a local Ventures group. The reviewers at the Ventures group will judge whether the idea is suitable for a non-disclosure agreement, and will base their decision only on the final report. The prospect of a design beginning the patent process, serves as further motivation to clearly express the ideas of the design. Due to the quantity and quality of writing required, as well as the revision process used, both of our senior design courses satisfy internal institutional writing requirements.

Ethics
As design teams are required to enter a medical environment, student witness first-hand the importance of medical ethics. All students are required to undergo the relevant HIPAA training at the mentor's medical institution.

Multi-disciplinary Teams
External mentors are active members of the design team and play a real role in all aspects of the design process. Students must learn to set and achieve goals, delegate responsibility, handle conflicting objectives, and function as a professional in a medical setting.

Course Assessment
External mentors have been used for every project in every offering of our senior design course. It is therefore not possible to fairly compare the external mentor approach to other possible implementations. The observations below reflect the opinions of the design team members.

Students
At the completion of the Fall semester students are asked to fill out an indirect assessment form. Averages (1-5 Likert scale, 1=disagree strongly, 5=agree strongly, n=15 from one year) from the five questions relevant to the role of the external mentors are presented below.

The fact that each team has a unique project that is developed by the team is a valuable characteristic of the senior design experience.	4.6
Weekly memos facilitated regular communication with the external mentors and faculty advisors.	3.5
The real-world, medical motivation for the projects was a valuable part of the experience.	4.4
Exposure to actual clinical and medical environments was a valuable part of this design experience.	4.1
My team's external mentor effectively contributed in the development of our project.	4.0
Are external mentors valuable to the senior design process?	Yes 14 No 1

At the completion of the Spring semester a meeting is scheduled between the students and a faculty member not involved in the capstone experience. Below is the list, generated by the students, of the benefits and challenges of working with an external mentor.

Benefits	**Challenges**
Different perspective on the problem	Mentors do not have a student mindset
Source of knowledge and experience	Scheduling conflicts
Exposure to the clinic	Mentor can affect project progress
Motivation	More work for students
Networking	No way to evaluate mentors

External Mentors
Mentors were invited to attend a department meeting following the completion of the Spring semester. Comments from the meeting are summarized below:

- It was not clear how critical we should be of student work
- Dedicating focus and time on project was sometimes challenging to maintain
- Not always clear of student expectations and deadlines
- Some students were not as enthusiastic as expected
- Important to have a course coordinator
- Much more to the mentorship than reading weekly reports
- Selection of mentors is critical to keep educational quality high
- Mentor education will be important for mentors new to the process

Faculty Advisors
At the same department meeting, faculty advisors were asked to share their observations:

- Differences in process and productivity varied greatly depending upon team dynamics
- Teams of three were more functional than teams of two
- Students initially disinterested in paperwork became convinced of the value in the end
- A plan must be ready to handle teams that go down an unproductive path
- Important to keep students taking the process (not just the product) seriously
- Real difference between roles of an external mentor and an external client

Based upon feedback from the design team members, the experience was largely positive. The general assessment of the department was that the educational benefits associated with external mentors far outweighed the challenges.

Recommendations for Implementation
For programs planning to incorporate external mentors into senior design the following suggestions are offered.

- External mentors should: 1) understand the primacy of the educational objectives, 2) be willing to sacrifice rapid progress for student experience, 3) remain invested throughout the project and 4) be willing to learn about the engineering design process. Identifying mentors that fit this profile is nontrivial and should begin well before the students are introduced to the mentors.

- Despite careful mentor selection, conflicts can arise between the educational goals and mentor expectations. Helping students navigate any conflicts is vital to the success of the senior capstone.

- An understanding of the institutional legal, IP and liability positions of both the university and medical institution is important to consider before progressing far into the design process.

- Due to many factors, projects may progress at different rates. Rather than penalize students for repeated delays that are out of their control, more flexible target due dates are set throughout the semester. One mechanism is for three or four dates to be set at which time multiple assignments are due.

- As a working prototype, with all documentation of the design process, is presented to a Ventures group, there is the possibility of a non-disclosure agreement with the intent to submit a patent application. The prospect of a patent in no way affects the grading process. Furthermore, students may be granted inventor status but may not assume any financial gain or liability.

- A clear plan should be communicated to the external mentors concerning the continuation of projects. In our implementation, a continuation of a project from a previous year would short circuit the educational value of the problem definition stage. Instead, four mechanisms have been established by which projects may continue. First, summer funds have been made available to rising sophomores or juniors wishing to work on a biomedical design project. Second, students may continue a project as an independent study for course credit. Third, a project may be refer to a state-funded Small Business Development Center (SBDC) located at our institution. Fourth, the project may be passed to the Institution for Leadership in Technology and Management (ILTM), also hosted at our institution.

- Due to the nature of our design sequence, the final functional deliverable is often not of the same scope as some other senior design deliverables. Students should be reminded early and often that their final product is of their own making and not the product of an imaginative professor, graduate student or external mentor.

Summary

Our program has successfully integrated external mentors into senior design teams at each step in the design process. The participation of the mentors and the level of commitment required of them have served to enhance our students' senior design experience. The most significant impact of the external mentor, however, is the opportunity to expose students to the importance of problem identification and definition as a pre-design step. We believe that providing students with the opportunity to identify their own design problems instead of providing them with a pre-written problem statement is more valuable to their engineering education. Although the addition of this pre-design step adds challenges for all members of the design team and even delays the start of the actual design process, the educational value is substantial. Our program will continue to refine and use the model outlined above.

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