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Learning to Identify Unmet Needs and New Product Opportunities*

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Design is a non-linear process that typically begins with the identification of a problem or unmet need. Once the problem is properly defined, customer needs can be determined, target specifications can be established, and potential design concepts can be generated. Needs finding is essential for established companies and start-up ventures and is an important skill for engineers to possess.

In many senior capstone design courses students choose from a list of project ideas presented to them at the beginning of the course. This provides more time to complete remaining phases of the design process, including building and testing prototypes. However, this practice bypasses the first phase of design and prevents students from gaining experience in defining problems and identifying unmet needs. Engineers working in industry will be involved in finding opportunities where technology can be used to solve problems, and will work closely with marketing, sales, and other personnel to identify new product development opportunities. They will also need to work with users of various products and technologies to identify problems and unmet needs. Students would be better prepared for careers involving new product development if, as part of their undergraduate education, they gained experience with the problem identification phase.

A new course for junior biomedical engineering students at Marquette University was developed in 2008 to expand their knowledge of and experience with the problem identification phase. The course includes several active and collaborative learning components and requires students to observe medical and surgical procedures in various clinical environments to learn how technology is used to solve medical problems. This experience develops the student's clinical literacy and their listening and ethnographic observation skills. They learn how to work with medical personnel to identify problems and unmet needs. This course allows students to experience the first phase of design and helps them develop design and entrepreneurial skills. It prepares students for careers involving the development of innovative new products for established or start-up companies.

Keywords: medical device design; needs finding; problem identification; new product development

1. Introduction

Most engineering graduates will work in industry where not all projects will be defined. They will be involved in finding opportunities where technology can be used to solve problems, and will work closely with marketing, sales, and other personnel to identify new product development opportunities. They will also need to work with users of various products and technologies to identify problems and unmet needs. Students would be better prepared for careers involving new product development if, as part of their undergraduate education, they gained experience with the problem identification phase of the design process [1–2]. Industry seeks employees with a 'holistic education experience' and supports changes to engineering education that bring 'real world engineering requirements, experiences, and tools into the classroom to prepare students for professional practice, with a view toward defining problems more broadly, in a more holistic fashion' [3]. This includes focusing on the customer, user, or patient, and understanding their needs when designing new products.

Very few capstone design programs are able to include all phases of the design process into a two-semester course sequence. Some programs may be front-loaded, where the emphasis is on problem and customer needs identification, development of target specifications, and concept generation. In these courses, teams may not be required to construct or test a prototype and a paper design may be accepted as a final deliverable. Other courses may skip the problem identification phase, and begin with identification of customer needs. Target specifications are then developed, concepts are generated and selected, and prototypes are built and tested to validate designs. In these courses the end deliverable is a functional prototype. A 2005 nationwide survey of capstone design course instructors reported that 56% of capstone design courses included developing and writing functional specifications, 48% included concept generation, and 37% included prototyping and testing as course topics [4]. Very few, if any capstone design courses require students to complete the design transfer or commercialization phases. Most students will gain experience with these phases while working in industry and not as part of a capstone design course.

One way of providing students with the opportu-

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nity to experience more phases of the design process is to expand design content to other parts of the undergraduate curriculum. Capstone design courses are typically taught in the senior year. It would be ideal for students to learn about (and possibly complete) the problem identification phase during their junior year (at the latest) in preparation for their senior capstone design course. This would not only expand their knowledge of the design process, but if done properly, could result in more student-generated capstone design projects. In 2005, only 15% of capstone design project ideas were student-generated [4]. Allowing students to choose their own projects and the approaches used to complete their projects increases motivation of the project team [5, 6]. This suggests that when teams propose their own project ideas, the outcomes may improve due to a stronger sense of project ownership, higher level of interest, and the team's desire to succeed.

2. Course design and rationale

2.1 Background

Students interested in careers involving the design of medical devices will need to become familiar with how devices are used in the clinical environment and the problems associated with their use. They will also need to learn how to identify opportunities where technology can be applied to solve a clinical problem. This can be accomplished by allowing them to observe clinical procedures in the clinical environment (ethnographic observation), listen to medical personnel (surgeons, physicians, nurses, and technicians) describe problems that need to be solved (articulated needs), and ask questions to try to uncover needs that exist, but have not been expressed (unarticulated needs).

Graduate programs involving clinical needs finding activities have been described, however, few if any exist for undergraduate biomedical engineering students [7–9]. Instructors for the biomedical engineering capstone design course at the University of California— Davis request veterinary and medical faculty to submit a one-page description of a problem they need help in solving [10]. This approach helps identify problems that could result in a capstone design project but does not involve students in the problem identification process. The course described here addresses this gap in design education and allows students to gain experience in needs finding and problem identification.

2.2 Course design

A new one-credit design course for junior biomedical engineering students at Marquette University, titled *Clinical Issues in Biomedical Engineering Design*, was developed and implemented in 2008 to expand their knowledge of and experience with the problem identification phase. It is an elective offered during the spring semester of the junior year and is completed during the semester prior to the senior capstone design course. The goals of the course are to 1) provide students with the opportunity to observe surgical and other procedures in the clinical environment, 2) help students learn how to listen to, speak with, and question medical professionals about problems with medical devices and other technologies used in the clinical environment, and 3) provide students with the opportunity to identify unmet needs and opportunities for new product development.

Due to hospital restrictions on the number of students allowed to observe clinical procedures per semester, class size was kept small (seven students in 2008, six in 2009, fifteen in 2010, and twenty in 2011). This provided time for the course instructor to expand areas for clinical observation and determine how best to accommodate a larger number of students when and if it were to become a required course for all junior biomedical engineering students.

The goals of this course are accomplished through visits to a local teaching hospital, class field trips, and guest speakers. After taking an exam on medical and surgical terminology, students sign up for visits to observe procedures in the Operating Room, Cardiac Catheterization Laboratory, Interventional Radiology Laboratory, Cystoscopy Suite, Intensive Care Unit, and other areas within Froedtert Lutheran Memorial Hospital (FMLH) in Milwaukee, WI. They also have the opportunity to observe clients with disabilities at the Milwaukee Center for Independence to learn about the needs of people with disabilities. Prior to their first visit, they are trained in what to expect and how to behave in the clinical environment, including operating room etiquette, safety procedures, and how to conduct themselves when working with medical personnel. When in the various clinical sites, they are allowed to observe procedures and ask questions when appropriate. They often meet with surgeons and nurses after the procedure to discuss problems and potential opportunities for device improvements or new products. Upon returning from the visit, each student is required to submit a clinical report detailing 1) what was observed, 2) the technologies used in the procedure, 3) any problems (articulated or unarticulated) that were experienced by the surgeon, nurse, or technician during the procedure, and 4) opportunities for new or improved products. Clinical visits are examples of active learning experiences in which students are engaged in the learning process and think about what they are doing [11]. They help develop the students' clinical literacy and give them practice in identifying problems and unmet needs.

Field trips include visits to the Marquette University School of Dentistry, Laparoscopic Surgery Simulator Laboratory (FMLH), and a Virtual ICU. Guest speakers, such as surgeons, nurses, dentists, and clinical engineers provide students with different perspectives on the use of and problems associated with medical and dental devices and technologies. Clinical engineers possess a wealth of experience and knowledge regarding the assessment, implementation, use, and maintenance of hospital-based healthcare technologies such as imaging systems, monitoring equipment, therapeutic devices, and surgical instrumentation. They can provide students with unique insight into problems with current devices. Other speakers discuss the needs of people with disabilities and the healthcare needs of the developing world. They are an excellent resource for learning about current problems and trends as well as ideas for potential new medical products.

The final deliverable for the course is a project proposal that provides students with a collaborative learning experience in which students work together in small groups toward a common goal [12]. It requires them to work in small groups to choose a problem of interest identified during one of their clinical visits and design a project around the chosen problem. The proposal includes information on potential customers and market size and a review of existing solutions to the problem. The purpose of the project proposal is to 1) help students learn how to design a project that could lead to a solution to the problem they have chosen and 2) serve as a potential source of student-generated senior design project ideas. Students are encouraged to allow ideas presented in the project proposals to incubate in their minds during the summer break and solidify into a senior design project by the start of the senior year in late August. One example of a project proposal addressed the problems of time inefficiency and patient safety. In response to their observations of the excessive amounts of time nursing personnel spent manually counting surgical sponges after surgical procedures the student team proposed a project to develop surgical sponges tagged with radio frequency identification devices (RFID) to be used with another device to count removed sponges and detect sponges remaining in the patient.

3. Student feedback

Student surveys were conducted in 2008, 2009, and 2010 to identify necessary course improvements and determine student perceptions of the course. No other data were collected. Students were asked to rate how well the course met the desired learning outcomes listed in the course syllabus. The results from students who responded to the survey are summarized in Table 1. Scores represent averages based on a five-point scale (5 = met outcome, 1 = did not meet outcome).

Students were also asked to provide comments on the value of the course deliverables, clinical observations, guest speakers, and field trips. Typical comments from students regarding guest speakers and clinical observations are listed below:

- *Extremely valuable to see the clinical issues from all of the different perspectives.*
- *Really liked the presentations by guest speakers, they provide the most insightful knowledge and got me really excited to go out there and create something.*
- *I think the wide range of information that was presented was very useful. I also think the course really helped me learn how to identify issues and opportunities while observing a procedure. I am very glad I decided to take the course.*
- *Clinical observations are the best way to learn about the problems/needs of the OR.*
- *The guest speakers throughout the course were very interesting and I think they really helped me increase my knowledge about biomedical engineering.*
- *What I enjoyed most about this course was the*

Table 1. Student feedback on course learning outcomes from 2008 to 2010. Scores are averages based on a five-point scale (5 = met outcome, 1 = did not meet outcome).

Year	**2008**	**2009**	**2010**
Students enrolled in class	7	6	15
Students responding to survey (n, %)	(4, 57%)	(3, 50%)	(9, 60%)
Upon completion of this course students will be:			
Familiar with the clinical environment and applications of technology in the clinical setting.	**5.0**	**4.7**	**4.7**
Able to identify clinical problems that can be solved through the application of technology.	**4.5**	**4.7**	**4.7**
Able to communicate with and listen to medical personnel, and identify customer needs and market opportunities for new medical devices and technologies.	**4.25**	**4.7**	**4.6**

hands-on involvement in the hospital setting. Being able to see a variety of medical procedures and gain an understanding of the problems medical professionals experience on a daily basis made this course worthwhile.
- *Getting the opportunity to observe medical procedures and actually spending time talking about problems with the technology with medical personnel, gaining hands on experience and observations were the most helpful.*
- *I really enjoyed this course. It has opened my eyes to new clinical problems and has really improved how I look at problems and go through steps of finding solutions.*

In summary, feedback from survey respondents indicated that students felt that the course learning outcomes were met and that the course provided them with valuable experience that would be helpful to their careers.

4. Discussion

4.1 Active and collaborative learning

This course employs active and collaborative learning methods to engage students in the learning process and improve student learning. Direct observation of surgical procedures, face-to-face discussions with medical personnel, and field trips are forms of active learning, and the team project proposal is a form of collaborative learning. The benefits of active and collaborative learning have been well documented in the literature and are reflected in the student comments documented in Section 3 above [13]. One student stated that observations of procedures were the 'best way to learn about the problems/needs of the operating room'. Another student who participated in field trips that allowed him to perform procedures such as drilling extracted teeth with dental drills and using the laparoscopic surgery simulator stated that 'gaining hands-on experience and observations were the most helpful' activities that supported learning in the course. Most students felt similarly about these forms of active learning.

Traditional lectures where students passively receive information from instructors are considered to be a less active form of learning [13] and are often not appreciated by students. However, in this course, student feedback was very positive toward guest speakers because they made students aware of the variety of perspectives and needs of different groups of users of medical technology, and motivated students to solve problems. Students felt that it was 'extremely valuable to see the clinical issues from all of the different perspectives represented by the guest speakers' and that the speakers provided 'the most insightful knowledge' and got students 'really excited to go out there and create something.'

4.2 Senior capstone design course

The two-semester long senior capstone design course at Marquette University is taught with computer, mechanical, electrical, and biomedical engineering students along with computer science students. Multidisciplinary project teams include students from any of these disciplines depending on the needs of the project. Each year, new biomedical engineering project ideas are generated and a list is compiled from which students can choose their top selections. Project ideas come from medical device companies, faculty, independent local entrepreneurs, and caregivers of people with disabilities. A small percentage (typically $<10\%$) of project ideas come from students.

As of August 2010, no project proposals generated from this course (taught in the spring semester) have become senior design projects in the fall semester. There are three reasons why this has occurred. First, and most significant, is the lack of project funding for student-generated projects. At Marquette University almost half of senior design projects are industry-sponsored and provide funding to project teams for prototype construction and other expenses. Faculty-sponsored projects provide funding, too. Other sources provide some additional funds but typically there is not enough to support all projects each year. For this reason, many students prefer to work on industry or faculty-sponsored projects that provide the funds needed to run a successful project. Second, team composition can affect the projects that students select. To some students, working on a team with people they know is more important than the specific project, project topic, or industry sponsor. This may cause students to abandon their own project ideas for the opportunity to work with friends or other compatible team members on another project of more interest to the other team members. Third, the popularity of the co-op program at Marquette University and its impact on the sequence of courses taken by students can affect students' choices of projects. Not all juniors completing the needs finding course will enroll in senior design during the following fall semester due to different co-op schedules. This can result in a breakup of the team of students that generated a project idea together (as part of the needs finding course) and planned to work on the project as a team during the senior design course.

Two approaches to increasing the probability of project proposals generated in this course being used as senior design projects would be to 1) encourage students to recruit interested and compatible students for their project team during the summer and 2) ensure that adequate funding is provided for student generated projects

4.3 Changes to the course

During the first three years the most common criticism of the course was that the amount of work required was too much for a one-credit course. As a result, the number of required clinical experience reports was reduced from three to two in the fourth year the course was taught. Other common comments involved conflicts between clinical visit schedules and students' course and work schedules.

Potential improvements to this course include 1) providing opportunities for students to observe a greater variety of clinical procedures and 2) allowing them to work together to write clinical experience reports which would increase the level of collaborative learning and could lead to improved learning outcomes and higher quality reports.

4.4 Assessment of learning outcomes

The results presented here are based on a summary of student comments received through voluntary surveys of students after completion of the course. The results are highly qualitative and were used to identify helpful course improvements and determine student perceptions of the course. More quantitative assessment methods are needed to measure student learning and determine how well the desired learning outcomes have been met.

4.5 Applicability to other disciplines

This course focuses on the early phases of the design process and was developed specifically for biomedical engineering students. However, the course concept and goals are easily adapted to design courses for students in other engineering disciplines. Engineers involved in new product development must be able to work with customers/users to learn of problems with current products and identify their customers' unmet needs. Faculty who teach students in aerospace, computer, electrical, mechanical, and software engineering (and other disciplines) can help them identify users of various products such as computers, cellular phones, bicycles, motorcycles, automobiles, airplanes, boats, manufacturing equipment, tools, software, home appliances, and many others. Working with industry partners, faculty can provide students with opportunities to observe customers using these products, interview customers about product-related problems, and discuss potential improvements to or needs for new and improved products. Students can then generate a list of problems, unmet needs, and opportunities for new product development. These unmet needs can serve as the basis for senior capstone design projects in any corresponding engineering discipline.

5. Conclusions

Through the use of active and collaborative learning methods, *Clinical Issues in Biomedical Engineering Design* provides students with the opportunity to improve their clinical literacy, become more familiar with how technology is used in the clinical environment, and learn how to observe, listen, ask questions, and work with medical personnel to identify problems, unmet needs, and opportunities for new medical devices and technologies. The ability to observe procedures, listen to customers, and identify problems and customer needs is vital to recognizing potential market opportunities and is highly valued by medical device (and other) companies. Interviewing and discussing potential design solutions with medical personnel helps students learn to communicate technical issues to non-technical people and work with people in non-technical disciplines, a helpful skill for students who will eventually work on multidisciplinary project teams in industry. Finally, the course allows students to gain experience in the earliest phase of the product development and design process and helps them develop additional design and entrepreneurial skills needed for careers in the medical device industry.

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