Work in Progress: Spicing Up Instruction of Professional Topics in Biomedical Engineering

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Olga Imas, Ph.D., is an assistant professor of biomedical engineering at the Milwaukee School of Engineering, where she teaches a variety of courses in biomedical digital signal processing, medical imaging, computing in biomedical engineering, biomaterials, anatomy and physiology. In addition to her academic responsibilities, she acts as a consultant to GE Healthcare for product development with emphasis on advanced imaging applications for neurology, cardiology, and oncology. Olga's technical areas of expertise include signal and imaging processing, and statistical analysis. In her previous and current product development roles, Olga gained extensive experience in clinical product management involving market analysis for new and existing imaging products, and clinical product marketing. She has experience in managing product evaluations at multiple clinical sites, and has a comprehensive knowledge of neurology, oncology, and cardiology imaging markets. She has established a number of strong collaborations with clinical experts in recognized neuroimaging and oncology centers.

Olga has earned her undergraduate degree in biomedical engineering from the Milwaukee School of Engineering in 1999, and a doctorate degree in biomedical engineering and functional imaging from the Joint Functional Imaging program at Marquette University and Medical College of Wisconsin in 2004. Prior to entering academia full-time in 2009, Olga completed a three-year postdoctoral fellowship in anesthesiology at the Medical College of Wisconsin, where she studied the effects of general anesthetic agents on brain function. She then worked at GE Healthcare as a product development specialist in CT and Molecular Imaging with emphasis on post-processing software applications for neurology, oncology, and cardiology. Olga has over twenty peer-reviewed publications, and three pending patents. Her professional interests include physiological mechanisms of Alzheimer's disease, anesthetic ablation of consciousness, and applicability of medical imaging in stroke and brain trauma.

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Dr. Larry Fennigkoh is a professor of biomedical engineering at the Milwaukee School of Engineering teaching graduate and undergraduate courses in medical instrumentation, biomedical engineering design, biomechanics, biostatistics, and human physiology. He is a Registered Professional Engineer and board certified in clinical engineering. He is also a member of the Institute of Electrical & Electronic Engineers, Association for the Advancement of Medical Instrumentation, American College of Clinical Engineering, American Society for Engineering Education, and an inducted Fellow within both the American Institute for Medical and Biological Engineering, and the American College of Clinical Engineering.

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Dr. Tritt has been the director of the Biomedical Engineering program at the Milwaukee School of Engineering (MSOE) since 2009. He has been teaching at MSOE since 1990. His Ph.D. is in Chemical Engineering from the Ohio State University as is his B.S. degree. He holds an M.S. in Biomedical Engineering, also from Ohio State. His research interests include biomedical applications of mass, heat and momentum transfer; medical product and process modeling; biomaterials; and entrepreneurship, innovation and commercialization in engineering education.

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Practical knowledge of topics such as FDA and international regulatory compliance, standards for medical devices, quality control in medical device manufacturing, and healthcare economics, are among the distinguishing skills of many biomedical engineers. Furthermore, industry highly values familiarity with these topics in biomedical engineering (BME) undergraduates; there is a growing demand for professionals who possess a combination of both technical knowledge and regulatory affairs [1]. However, it is challenging to instruct students on these inherently dry topics, particularly in the absence of practical applications.

Recognizing that expertise in any of these areas is an impractical goal for undergraduate students, BME programs have implemented several different approaches to provide a working knowledge of these topics to equip graduates for work in the medical device industry. These approaches range from entire courses devoted to singular topics, such as medical device regulation [2], to lectures integrated into the capstone design courses [3]. The Milwaukee School of Engineering BME program has traditionally followed the latter approach. The approach was efficient, requiring no additional course credits, and it was effective in targeting mature students who had some appreciation for the importance of the topics. However, data collected from students through surveys conducted in the design courses and at the time of graduation revealed several disadvantages of the approach, including:

1. Coverage of the topics was not always timely in its application to design projects, because projects progress at different paces.
2. Students struggled to remain attentive to lectures that focused on the background and theoretical application of these topics.
3. Students often viewed these presentations as distractions at a time when they preferred to devote their time to progressing technically on their design projects.
4. Many students exited the program lacking confidence in their ability to apply these topics to real applications despite a general requirement that students consider them all in their design documentation.

As part of a recent major curriculum revision, our faculty created a course entitled Professional Topics in BME. All students are required to take the course prior to beginning the capstone design sequence. The specific objective of the course is to improve overall student confidence and understanding of the topics by addressing the issues above. The purpose of this article is to describe the approach, in particular how it attempts to alleviate the issues above, and a plan to assess its success as it is phased in to the curriculum.

Course Description

Our Professional Topics in BME course is a two-credit course that runs in the fall trimester. It is on track for junior year students, who begin the four-trimester senior design sequence the following spring trimester. The course meets for two lecture periods for each of the ten weeks in

the term. It runs as a single section of approximately 50 students, meeting in a large lecture hall. The course outcomes are as follows:

- Identify what constitutes human subject research and describe the IRB approval process
- Identify ethical considerations for scenarios involving the medical device industry
- Identify relevant sources of standards and codes related to specific medical devices
- Identify ways to mitigate patient risk associated with medical devices
- Identify whether a device is an FDA medical device and its likely FDA classification
- Describe FDA Quality System Regulation design controls and identify when they apply to the medical device design and manufacturing processes
- Identify methods to ensure quality in the manufacture of medical devices
- Use formal methodology to identify design requirements
- Describe the options for protecting the intellectual property of medical device designs
- Identify differences in regulatory approaches between the United States and other nations that might impact accessibility of these devices to patients.
- Articulate different viewpoints of a current controversial issue, including how each view impacts marketing and accessibility of medical devices.

The structure and timing of the course was intended to address two of the concerns raised by students. First, coverage of the topics was reduced in the design courses to eliminate the sense that it took away from time to achieve technical progress on projects. Second, covering all topics prior to the design sequence guaranteed that all students were exposed to each topic prior to the students' need to apply them to their individual design projects.

A total of twenty presentations were planned to address the various topics covered in the course outcomes. Experts were enlisted from industry or, in a few cases, different academic departments at our university to deliver the majority of the presentations in the course. As the use of active case studies (as opposed to reviewing historic case studies) is recognized as an effective approach toward teaching several of these topics [2, 4], the course coordinator proposed a hypothetical medical device to serve as a case study, which was introduced to students in the first lecture. The device was then applied, in the form of discussion or written assignments, to the majority of the topics throughout the course. In its initial offering, the case study involved an intravascular glucose sensor that could transmit blood glucose readings to an external receiving device in diabetic patients. The rationale for including guest lecturers and a single unifying case study was to improve student interest and engagement in the presentations. Lecturers from industry add credibility and relevance to subject matter [5]. Case study discussions could add further contextual relevance to each topic. In addition, use of an ongoing case study provided guaranteed timeliness of each topic since they were immediately tied to an application.

One final intention of this course was that it would provide an opportunity to consolidate the assessment of several of the program's student outcomes that are difficult to perform in traditional didactic courses. Standard assessment tools, mostly associated with targeted written assignments in the course, would allow for better consistency in data collection used as part of the program's continuous improvement process.

Assessment Plan

The objective of the new course is to improve students' attitude and ability to apply the various topics covered in the course, both in the senior design project and at the time of graduation. Thus, assessment is primarily intended to capture students' perceived knowledge and abilities before and after the senior design sequence. Students who enrolled in the initial offering of the course will be surveyed as they begin their first senior design course to specifically capture: (1) their perceived understanding of each topic; (2) their perceived ability to apply each topic; and (3) their appreciation for the importance of each topic. A similar survey will be conducted of the same students upon their completion of the senior design sequence to determine if their application of the material reinforced their knowledge and appreciation of the topics. Furthermore, the same survey will be conducted of the final cohort of students following the previous model of covering the topics solely in the senior design courses upon their completion of the design sequence. Questions will also be asked of seniors during their routine group exit debriefing to provide a second method of assessing students' attitudes and perceptions of the topics. To provide an additional means of assessing students' abilities, design instructors will complete assessment forms for each student, addressing issues such as whether students presented a reasonable regulatory summary for their project, approached human subject research appropriately, and used a logical approach to arrive at clear design inputs. Finally, as the above longitudinal plan will require time to acquire data and draw conclusions, anecdotal evidence of students' perceptions has been and will continue to be collected from the end of course surveys that students complete in the final week of the Professional Topics in BME course.

Preliminary Results

In its first offering, 47 students enrolled in and completed the course. Eleven guests presented in the course, with two others needing to cancel their presentations. Lessons were learned about the challenges of scheduling a large number of guest presenters in a course. Nevertheless, the anecdotal comments provided by students in the end of course survey about the content and approach of the course were overwhelmingly positive. Most notably, students reacted very positively to the fact that information was coming from industry experts. Students also commented that on several occasions, guests stressed the importance of topics covered earlier in the course. Finally, students thought that the ongoing case study was a good approach to demonstrate applicability of the various topics. While minor changes are planned for the second offering, the inaugural offering was overall considered successful by the program's faculty.

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[3] R. H. Allen, S. Acharya, C. Jancuk, and A. A. Shoukas, "Sharing best practices in teaching biomedical engineering design," *Ann. Biomed. Eng.*, vol. 41, no. 9, pp. 1869-1879.
[4] B. Perlmann and R. Varma, "Teaching engineering ethics," in *Proceedings of the 2001 ASEE Annual Conference & Exposition, Albuquerque, NM, USA, 2008*, pp. 6.940.1 – 6.940.11.
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