Spicing Up Instruction of Professional Topics in Biomedical Engineering

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Full preparation for careers in the medical device industry requires that biomedical engineers enter the workforce with not only design and technical skills but also working knowledge of topics such as device regulation, standards, intellectual property, healthcare economics, and documentation. There is growing demand for engineers who possess a combination of both technical knowledge and understanding of topics such as regulatory affairs [1] and engineering standards [2]. Although the combination of technical and "soft skills" can be an important distinguishing characteristic of biomedical engineers in industry, it is challenging to effectively teach students professional topics in an undergraduate biomedical engineering curriculum that also attempts to cover the breadth of engineering and life science topics that is the hallmark of the discipline.

Recognizing the importance of professional topics, students are often required to implement them in their culminating capstone design project. A common approach is to teach the topics in the capstone design courses themselves, often by providing didactic sessions covering each topic just before students are asked to apply it [3], [4], [5]. However, this paradigm of lecturing on a topic once and expecting students to understand and apply the concept has not always proven to be effective. Repetition in instruction and practice is a strategy commonly employed to improve depth of understanding and long-term retention of knowledge [6], [7]. Considering the benefits of early exposure, a recent panel discussion on standards education at the *Capstone Design Conference* in 2012 recommended that standards education should start earlier in the curriculum [8], and efforts have been undertaken to introduce engineering standards in earlier biomedical engineering courses [9], [10]. The idea of devoting separate courses to these topics has also emerged, including courses focusing on FDA medical device regulation or standards [11], [12]. Separate courses have also been implemented to cover an array of these professional topics either concurrently with or as a prelude to capstone design [13], [14]. However, the benefits of such an approach have not previously been assessed and reported in the literature. As part of a recent curriculum revision, our undergraduate program introduced a required course called *Professional Topics in Biomedical Engineering* taken during the junior year prior to the first capstone design course. This study investigates the benefits of inclusion of this course relative to the traditional approach of covering the topics exclusively during the capstone courses, and it explores the progressive nature of student learning of these topics when taught in a separate course and later reinforced in the capstone design project.

Course Description

In designing the new Professional Topics in Biomedical Engineering course, our faculty considered feedback collected from students following the previous curriculum. Feedback was collected through surveys conducted in the design courses and at the time of graduation, and it revealed several disadvantages of covering these topics exclusively in the design courses, including:

1. Coverage of the topics was not always timely in its application to design projects, because projects progress at different paces.
2. Students often viewed these presentations as distractions at a time when they preferred to devote their time to progressing technically on their design projects.
3. Students struggled to remain attentive to lectures that focused on the background and theoretical application of these topics.
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.

Introducing the professional topics in a separate course prior to capstone design alleviated the first and second concerns above. In order to address the concerns related to the effectiveness of instruction, including the challenge of maintaining the attention of students while teaching these inherently “dry” topics, two strategies were employed in the course design.

First, 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. The use of guest lecturers adds credibility and relevance to subject matter [15]. Additional benefits of the use of guest lecturers in biomedical engineering courses include the emphasis it places on the need for a team of experts to solve complex biomedical engineering problems and the exposure it provides for students to different industry segments in the discipline [16]. Most of the guest lecturers were selected from the course coordinator’s professional network. They consisted mainly of individuals familiar with the BME program and its goals, including alumni, four members of the program’s Industrial Advisory Committee, and several faculty and staff members of the university. About half of the presenters had given guest presentations in the program at some point before. While the course coordinator shared the topic description with each presenter, the particular presentations and delivery methods were not reviewed by the course coordinator in advance.

The second strategy employed was the introduction of a hypothetical novel medical device to serve as a case study to demonstrate context for each topic as it was covered. 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 [9], [17], [18]. The case study was introduced to students in the first lecture and then applied, in the form of discussion or written assignments, to most of the topics throughout the course. The ongoing case study also provided guaranteed timeliness of each topic since they were immediately tied to an application.

The course developed, called *Professional Topics in Biomedical Engineering*, is a two-credit course that runs in the fall trimester. It is on track for junior year students, who begin the four-quarter senior design sequence the following spring quarter. The course meets for two lecture periods for each of the ten weeks in the term. It runs as a single section of approximately 35-45 students in a lecture hall to accommodate the use of guest presenters. In addition to a few topics related to career preparation, topics covered in this course include the ten given in Table 1. The order of the topics varied, depending on the availability of guest presenters.

Table 1: Topics covered in Professional Topics in Biomedical Engineering Course

Topic Number	Topic Identification	Description Presented to Students on UIC Survey
1	Intellectual Property	What it means to patent a product. What can be patented in the U.S. and what legal protections a patent provides. How to conduct a patent search.
2	FDA Regulation	How the FDA defines and classifies devices. The various regulatory pathways to market and how to determine which applies to a device. Basic quality design control requirements for all medical devices.
3	Medical Device Standards	The purpose of conforming to standards in design. How to determine which standards apply for a given device. Where to find standards common for medical devices.
4	Hazard Analysis	Reasons for applying hazard analysis during the design of a medical device. How to conduct a hazard analysis. The preferred approaches for mitigating risk associated with a hazard.
5	User Requirements and Design Inputs	The definition of user requirements and design input requirements (a.k.a. product design specifications, engineering characteristics). How to use systematic approaches to define design input requirements based on user requirements and other constraints. How to phrase design input requirements in such a way that they can be individually tested for verification.
6	Design for Manufacture	Different manufacturing options used in the medical device industry. How to apply manufacturing constraints in the design of a medical device, including quality control considerations and sterilization if applicable.
7	Healthcare Economics	Basic supply versus demand economic theory and unique economic driving forces in the healthcare industry and how they affect economic decisions for a medical device. How private and government healthcare insurance pay for medical devices.
8	Globalization of Medical Devices	Basic differences in regulation, standards, and intellectual property between the U.S. and other developed countries, and what additional steps are necessary to market and manufacture a medical device in a different country. Design consideration to make a medical device accessible to individuals and healthcare facilities in under-developed nations.
9	Ethical Consideration in Medical Device Design	Where to find applicable codes of ethics for biomedical engineers. Interpretation of the intended meaning of statements in the applicable codes of ethics. How to identify real-life situations for which codes of ethics apply. How to apply codes of ethics and other ethical considerations when

		a dilemma arises. How to conduct human subject research following ethically-responsible protocols.
10	Documentation	The purpose of thorough documentation in the medical device design process. Following documentation approaches that comply with FDA guidelines.

Study Objectives and Methods

The overall objective of this study was to determine the effectiveness of the curricular approach described above. Specific objectives were as follows:

1. Determine whether the new curricular approach was more effective than the previous curricular approach in covering professional topics in biomedical engineering.
2. Determine whether the new course results in increased knowledge of professional topics that is retained and then reinforced in students' capstone design experience.

Ideally, effectiveness of covering professional topics would measure students': (1) understanding of the topics, (2) appreciation for the importance of the topics, and (3) confidence in applying knowledge of the topics in the real world. As such, an assessment tool, which we refer to as the UIC Survey, was developed to ascertain students' Understanding of (U), perceived Importance of (I), and Confidence in applying (C), the ten major topics covered in the course listed in Table 1. An excerpt from the UIC survey (corresponding to *Topic 4: Hazard Analysis*), illustrating the format in which items were presented to students, is given in Figure 1. Table 1 lists the precise description for each topic given to students on the UIC Survey.

Topic 4: Hazard Analysis. ***Reasons for applying hazard analysis during the design of a medical device. How to conduct a hazard analysis. The preferred approaches for mitigating risk associated with a hazard.***

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I have a good conceptual understanding of this topic.	O	O	O	O	O
I believe understanding of this topic is important for a biomedical engineer.	O	O	O	O	O
I feel confident that I could apply this topic as would be expected for an engineer in industry.	O	O	O	O	O

Figure 1: Excerpt from UIC Survey corresponding to Topic 4.

An experimental design, approved by the university Institutional Review Board, identified three time points in the curriculum at which all students enrolled in on-track biomedical engineering courses were offered the same UIC Survey anonymously. These time points were at the beginning of the professional topics course (Pre-Course), at the beginning of the four-quarter capstone design sequence (Pre-Capstone), and at the end of the capstone design sequence (Post-Capstone). The Pre-Capstone survey was conducted approximately four months after the completion of the professional topics course. This time point was chosen for the administration of the mid-point survey, rather than immediately after the course, to assess students' thoughts and knowledge of the topics retained for the beginning of their capstone courses.

As one other instrument of measuring effectiveness, questions were added to the students' online senior exit survey, taken within a month of graduation. This survey instructed students to "Please indicate whether you agree with the statement that each of the following professional topics was taught effectively in your BME curriculum track." It then lists each of the ten professional topics in Table 1, accompanied by the same Likert rating system as the UIC Survey.Surveys have been administered since the beginning of the 2018-2019 academic year and have involved three different student cohorts, capturing a transition from students taking the previous curriculum track in which professional topics were covered in a more conventional format throughout the capstone design courses on an as-needed basis (Cohort 1) to the new curriculum featuring the separate professional topics course (Cohorts 2 and 3). The nature of the curricular transition and the timing of courses in the curricula have allowed three comparisons to address the study objectives described above. These comparisons are detailed in Table 2. The same faculty member has organized the Professional Topics in Biomedical Engineering course since its inception. The capstone design courses are taught by a rotation of faculty, so all three cohorts experienced a different set of two or three faculty members. However, all faculty involved had taught the capstone design sequence at least one previous time, and the faculty follow a common outline for the courses.

Table 2: Comparisons performed to address study objectives.

Comparison Group 1	Comparison Group 2	Assessment Tool(s)
Cohort 1, Post-Capstone	Cohort 2, Post-Capstone	UIC Survey, Senior Exit Survey
Cohort 2, Pre-Capstone	Cohort 2, Post-Capstone	UIC Survey
Cohort 3, Pre-Course	Cohort 3, Pre-Capstone	UIC Survey

Comparison of UIC Survey results were conducted at a broad level and at a detailed level for each pair of groups identified in Table 2. For all analyses, Likert ratings were converted to a 1-5 scale, from strongly disagree to strongly agree. For the broad comparisons, for each of the three dimensions (U, I, C), ratings for all ten topics were summed. These summed scores were statistically compared between the two groups of interest using Mann-Whitney tests to compare population medians with adjustments for ties. Although parametric tests can be used to compare Likert rating data under certain circumstances [19], only some of the data sets in this study, for which sample sizes varied between 22 and 47, passed normality criteria. Therefore, a non-parametric test, the Mann-Whitney test, was used for inter-group comparisons throughout this study. For the broad-level comparisons, medians were considered to be significantly different if corresponding p-values were below 0.05.

For the detailed comparisons of specific topics Mann-Whitney tests were also performed, based on Likert ratings for *individual topics* in the UIC survey. Because ten comparisons were being made at once for a given dimension, the Holm-Bonferroni method was applied to account for multiple comparisons at an overall significance level of 0.05.

The same broad- and detailed-level comparisons were conducted for the Senior Exit Survey consisting of ten survey items.

Results

The first objective of this study was to determine whether the new approach toward covering professional topics in a biomedical engineering curriculum was associated with improved measures of effectiveness of topic coverage. Both the UIC Survey and the Senior Exit Survey were administered to the final cohort of students on the previous curriculum and first cohort of students following the new curriculum with the professional topics course. To show the results of the UIC Survey qualitatively, the percentage of students agreeing or strongly agreeing with each survey item was computed, as was the percentage of students disagreeing or strongly disagreeing. The remaining students were binned into a third neutral category. Graphs showing all thirty survey items for both cohorts are shown in Figure 2.

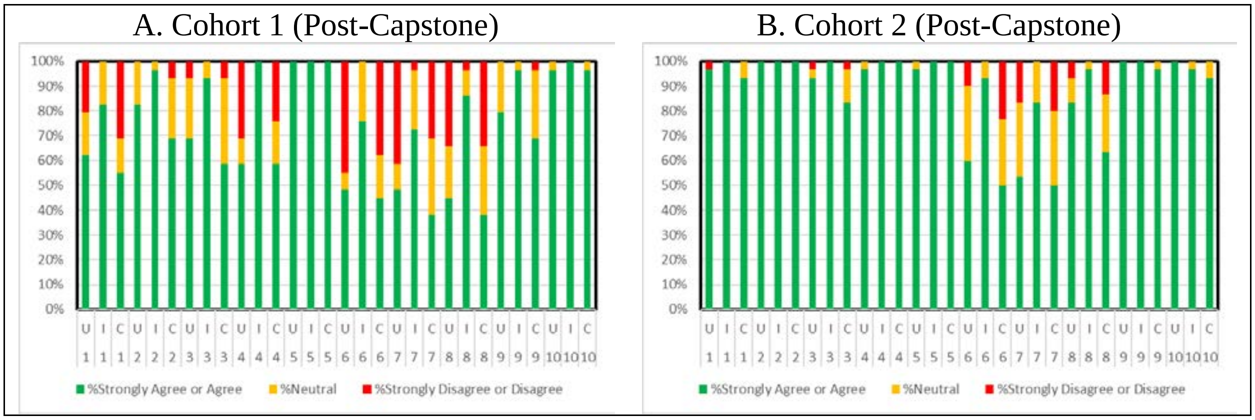

Figure 2: UIC Survey post-capstone qualitative results for (A) Cohort 1, which followed the previous curriculum (n=29), and (B) Cohort 2, which followed the new curriculum (n=30).

Based on the summed ratings across all topics, students in Cohort 2 reported a significantly higher rating of understanding (U) compared to those in Cohort 1 ($p<0.001$). The specific topics with improved ratings included topics 1, 2, 3, 4, 8 and 9. Students in Cohort 2 also reported significantly higher ratings for confidence in applying topics (C) compared to those from Cohort 1 ($p=0.001$). Specific topics with improved confidence were topics 1, 2, 3, 4, 5, 8 and 9. There was not a significant difference in appreciation of importance (I) of the topics collectively, nor any topic individually.

In addition to the UIC survey, Cohort 1 and Cohort 2 also completed the Senior Exit Survey at the completion of their capstone design courses. This survey asked students to rate the quality of coverage of the ten topics covered in the professional topics course. There was a statistically higher total score across the ten topics for Cohort 2 compared to Cohort 1 ($p<0.001$), with all ten individual topics having significantly higher ratings for Cohort 2. Figure 3 shows the qualitative comparison of these survey data.

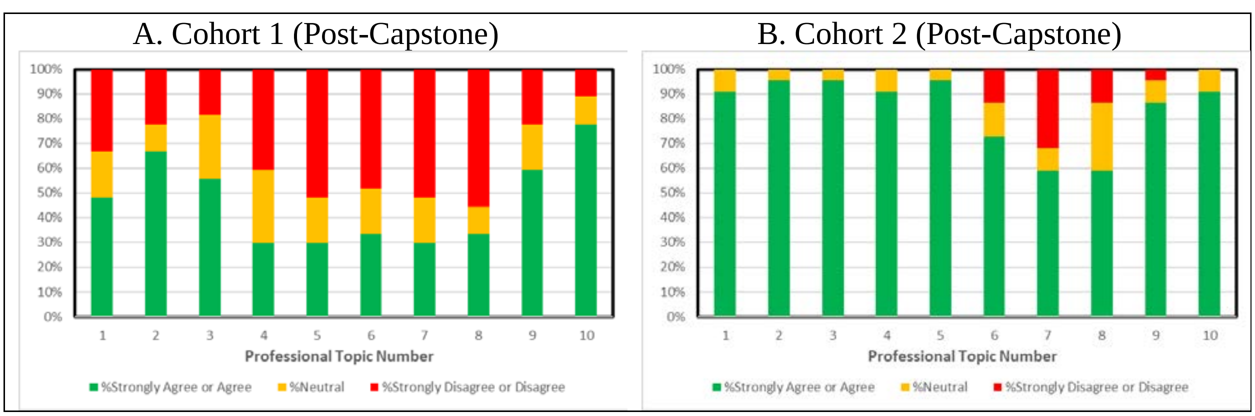

Figure 3: Senior Exit Survey post-capstone qualitative results for (A) Cohort 1 (n=27) and (B) Cohort 2 (n=22).

To determine whether there were improvements in the three dimensions of knowledge for each topic associated with engaging in the professional topics course, comparisons of UIC Survey Data were made before the course (Pre-Course) and before the capstone courses (Pre-Capstone) for Cohort 3. The UIC Survey results are shown qualitatively in Figure 4. There were statistically higher summed scores for the Understanding ($p<0.001$) and Confidence ($p<0.001$) dimensions after the course compared to before the course. For each of these dimensions, all ten topics showed statistically higher scores after the course as well. For the Importance dimension, neither the total score nor any of the individual topic scores were significantly different between the two time points.

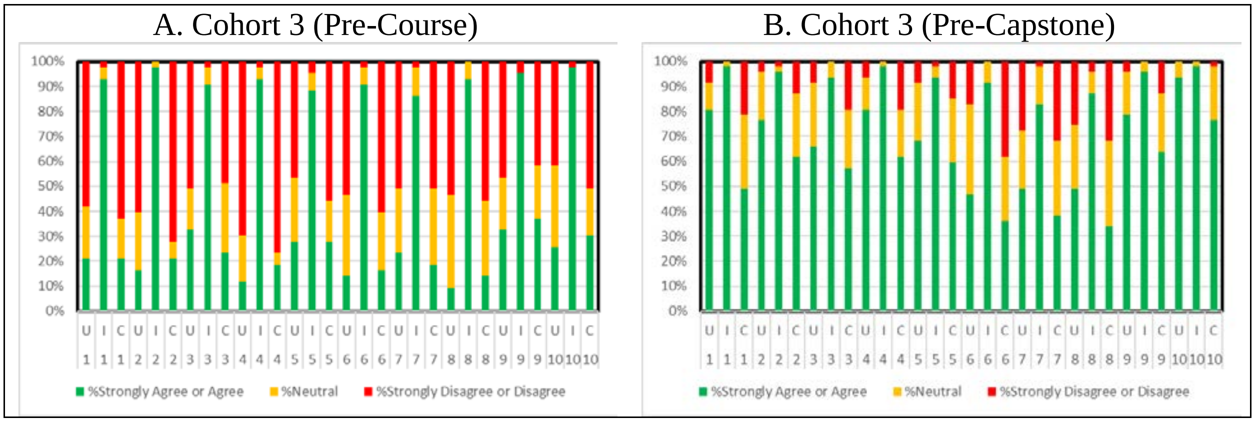

Figure 4: UIC Survey results for Cohort 3 (A) before taking the professional topics course (n=43) and (B) approximately four months after the course, prior to the capstone design courses (n=47).

Cohort 2 was used to compare UIC Survey data before and after the capstone design courses. These results are shown qualitatively in Figure 5. There were statistically significant increases in total score for both the Understanding ($p=0.002$) and Confidence ($p=0.002$) dimensions, but not for the Importance dimension. Topics 1, 3, 4 and 6 had increases in scores for Understanding between the two groups. Interestingly, two topics (3 and 5) had increases in score for Importance, while no individual topics had statistically significant increases in score for Confidence.

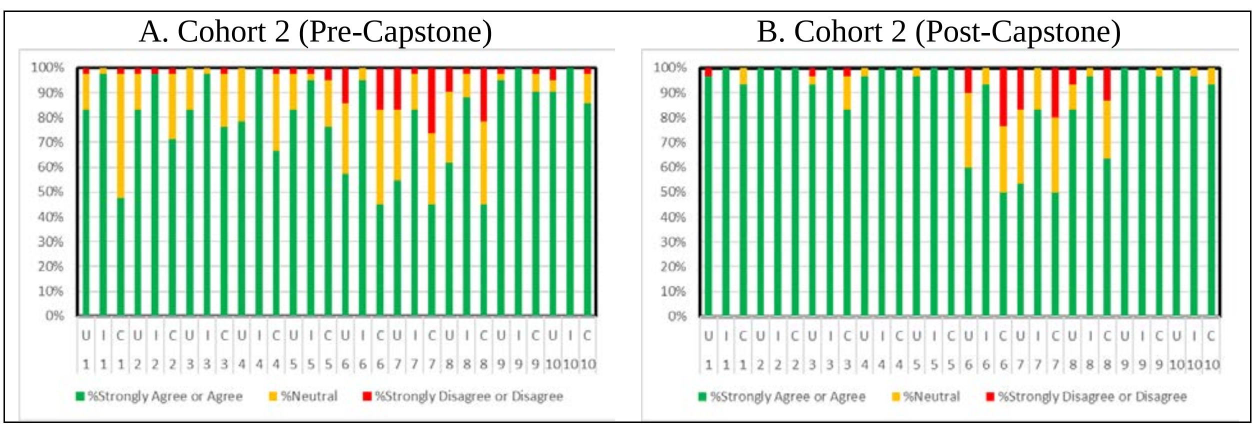

Figure 5: UIC Survey results for Cohort 2 (A) before (n=42) and (B) after the capstone design course sequence (n=30).

To assess inter-cohort differences, Pre-Capstone UIC Survey results were compared between Cohort 2 (Figure 5A) and Cohort 3 (Figure 4B). While differences in summed scores were found for the Understanding (p=0.027) and Confidence (p=0.01) dimensions, there were no statistically significant difference in scores for the Importance summed score, nor for any individual topic in any of the categories.

Discussion

In this study, we sought to determine whether a change in the approach by which professional topics are covered in a biomedical engineering curriculum was beneficial for students. A new survey instrument, the UIC survey, was developed to rate students' self-reported levels of understanding of, appreciation of importance of, and confidence in ability to apply each of the ten topics covered in the new course. At the completion of the curriculum, those who experienced the dedicated course reported higher levels of understanding of the topics as a whole, as well as higher levels of confidence in applying those topics in the real world. Among the topics for which students did not report improvements were topics for which coverage in the professional topics is limited to one lecture, with no assignments (Design for Manufacture and Healthcare Economics), and one topic, Documentation, which already had extremely high ratings in the previous curriculum, because it has been heavily emphasized historically in the curriculum. These same students also reported higher levels of satisfaction with how all ten of the topics were taught in the curriculum.

To determine whether the new curricular approach led to increases in knowledge and appreciation of the professional topics that were transient or sustained and reinforceable, the UIC survey was administered at three time points in the curriculum. Comparisons of results for surveys taken before the professional topics course and approximately four months after the completion of the course showed that understanding and confidence in applying the topics were not only higher after the course, but the gains remained one academic term after completion of the course. These improvements were noted for every topic covered in the course. The intervening term in the curriculum does not include coursework to specifically address any of the professional topics. Participation in the capstone design experience led to further gains in understanding the professional topics and in confidence in applying the topics as a whole. Understanding was reinforced in capstone design for several topics for which students are required to apply to their respective projects, including intellectual property considerations, medical device standards, hazard analysis, and design for manufacture. Interestingly, none of the individual topics were associated with reinforced confidence as a result of the capstone design experience.

None of the comparisons yielded increases in students' self-reported appreciation for the importance of professional topics, with the exception of two specific topics in the pre-capstone/post-capstone comparison. Inspection of Figure 4A shows that students tend to have a high level of appreciation for these topics even prior to the course in which many of these topics are introduced. It is possible that students perceive topics to be important based on knowledge that the topics *will be* covered in the curriculum, even if they do not understand the topics. It should also be noted that student perception is likely dependent on the background and aspirations of the students. Our university is a small private midwestern university, and approximately 80% of the graduates from our BME program go straight into industry. Factors such as a high ratio of pre-med or research-oriented students or a high ratio of students who participate in internship or co-ops programs could impact the influence of the professional topics course highlighted in this study.

Due to the timing of the curricular transition and sequencing of courses, we were unable to track a single cohort of students through all three timepoints during the course of the study. However, we were able to make intra-cohort comparisons between the first two time points (Pre-Course and Pre-Capstone) and the second two time points (Pre-Capstone and Post-Capstone). We also showed that results at a given time point were mostly consistent between cohorts. In the comparison of Cohort 2 and Cohort 3 at the Pre-Capstone time point, there were statistically significant differences in the summed scores for the Understanding and Confidence dimensions, but the level of significance was much lower than any of the others observed for other comparisons. Furthermore, none of the thirty individual item ratings were different between the two groups at the same point, demonstrating consistency that is further supported by visual comparison of Figure 4B and Figure 5A.

While this study addressed student perceptions with respect to the knowledge of the professional topics, it did not measure whether or not student abilities to apply the topics improved. Previous work has shown that ability to correctly apply one of the topics, engineering standards, requires that students are not only exposed to the topic multiple times, but that they are required to apply the topic in different courses in a curriculum [9]. In our professional topics course, some opportunity is given to explore how topics apply to the ongoing hypothetical case study, but it is not a rigorous application. The authors created an additional assessment instrument, completed by respective capstone design instructors, to rate how well students applied each of the topics in the context of their capstone projects. Unfortunately, the instrument was found to be unreliable, as its results were most dependent on the particular instructor performing the ratings. Therefore, we were unable to judge whether the new curricular approach benefits students in terms of their ability to apply the topics. Future work will concentrate on rating student performance more reliably to address this important dimension of learning.

As stated above, the authors were intentional in their timing of the midpoint survey. Rather than conduct it at the conclusion of the professional topics course, when reported knowledge gains could be transient, we conducted it at the end of the following academic term, just prior to the first capstone design course, to determine the sustained gains from the course. Indeed, the gains were significant, and we attribute the retention of understanding, at least partly, to the mode of delivery of the course content, particularly the use of guest presenters and reference to an ongoing case-study. Both of these methods have documented teaching benefits in biomedical engineering topics. Anecdotally, feedback from students at the completion of the course indicated particular appreciation of the many guest presenters from industry who presented on the professional topics.

While the use of guest presenters was viewed favorably by students overall, the fact that not all presenters were fully vetted beforehand led to some challenges and opportunities for refinement. For example, two of the topics for which the first cohort of students taking the course did not report significant improvements were Design for Manufacture and Healthcare Economics. Recognizing room for improvement through the student surveys and observations by the course coordinator, alterations were made for coverage of these topics for the second offering of the course. Specifically, a new presentation on quality has been added to complement the focus on manufacturing processes, and the course coordinator developed a new presentation for healthcare economics that better aligns with the issues most salient to the medical device industry. Faculty will continue to monitor student views of the various topics and use survey data to identify opportunities to improve. This approach of making gradual alterations in the selection of presenters and allocation of class time to topics is chosen over providing constraints to speakers in order to allow them to organically emphasize points based on their professional experiences.

An additional benefit of the professional topics course is that it allows for some consolidation of assessment of achievement of student outcomes for program continuous improvement and compliance with ABET criteria [20]. Program faculty have identified several performance indicators relevant to the course that align with student outcomes both before and after a recent revision of student outcomes by ABET. It should be noted, though, that students generally continue to hone most of the professional skills after this junior-level course, so assessment data collected in this course is not used exclusively to measure attainment of student outcomes at the time of graduation.

Based on the results of this study, the authors believe that allocating time and credits to specifically cover professional topics, prior to their application in the capstone design courses, is a worthwhile investment. While it is challenging to find space and credits in a curriculum for which breadth and depth are essential key features, this approach ensures that students are prepared to address these important topics in their capstone projects. Furthermore, the capstone design experience can then further reinforce the students' level of understanding of these topics to prepare them to be successful engineers in the medical device industry.

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