Work in Progress: Development of a Medical Devices Course for Sophomore Biomedical Engineering Undergraduate Students

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Introduction

The biomedical engineering (BME) workforce requires competency in professional and technical skills. BMEs often use knowledge in design, administration and management, and customer needs assessment [1]. Typical work activities of a BME include analyzing data or information, organizing and planning work, determining compliance with standards, building teams, and drafting and specifying technical device parts [1]. The undergraduate BME capstone design course is often used as a "catchall" to develop these critical professional skills; however, to build competency, it is recommended that these skills be practiced throughout the curriculum, not just at the end [2]. Unfortunately, in many BME undergraduate programs, due to the high number of prerequisites, BME-specific courses are not the focus until junior year [3]. Therefore, there is a need for earlier and explicit training to build and reinforce these skills and enhance BME professional identity [2]. To address this need, we developed a core, sophomore-level, medical devices course in which students simulate the engineering teams found in industry to develop workplace-ready skills. The goals of requiring this new course in our curriculum are to

- Increase students' biomedical engineering professional identity, which we anticipated would occur as a result of earlier exposure to BME roles and skills.
- Increase students' industry-relevant skills (described in the course learning goals).
- Introduce students to the variety of career opportunities within medical devices industry.

The scope of this Work in Progress is to describe students' perceptions of the pilot course.

Course Description

BMEG260: Introduction to Medical Device Design was piloted as an elective in spring 2022 and enrolled 10 students, prior to becoming a required course for all sophomore-level BME undergraduates in spring 2023. Students were notified about the pilot through emails sent to all BME undergraduates; any second year BME was eligible to register. The course learning goals and performance indicators are provided in Appendix A.

To achieve these learning goals, students worked in teams of 3-4, each with a defined role modeled after those from the medical devices industry. Teams explored three medical device units in spring 2022: surgical staplers, breast pumps, and stents. Each 4-week unit consisted of four key topics: needs identification, design requirements, regulatory, and ethics. The course focused on understanding these existing devices and their limitations, not on designing a new device. To scale up the needs-finding benefits of traditional clinical immersion courses while avoiding some of the restrictions [5]-[7], students accessed the voice of the customer (VoC) through pre-recorded video interviews conducted by the instructor. Each unit included 4-5 VoC interviews with medical device users and clinicians, which students used to define unmet needs of existing devices and propose design requirements. For all units, students touched, manipulated, measured, and/or used the actual medical devices to learn how they work and better understand their form and function. They recreated device components using SolidWorks. Embedded throughout the semester were professional proficiency lessons on teamwork and project management. Ten guest speakers spoke on topics such as the medical device design

process and industry roles, teamwork, business considerations and entrepreneurship, environmental impacts, and the U.S. healthcare system. The pilot was scheduled to meet twice a week for 50-minute lectures and once a week for a 1-hour 40-minute studio. SolidWorks lessons were delivered in an asynchronous format (video recordings).

At the end of each unit, student teams submitted deliverables using templates modeled after company forms: Product Initiation Request form, Design Inputs table, Design Details form, and Failure Mode and Effects Analysis (FMEA) table. The deliverables, mapped to the learning goals (Appendix A), included writing a need statement based on the VoC; examining regulatory, ethics, and impacts of engineered solutions; creating design inputs; summarizing design details and recreating a CAD model of an existing product; and identifying potential failure modes of an existing product. Additional assessments tied to learning goals included maintaining a design history file (DHF), team norms, peer evaluations, individual CAD assignments, and individual low stakes assignments on FDA pathways, ethics, and manufacturing methods.

Focus Group Evaluation

A focus group discussion (Appendix B) was conducted by a professional external evaluator at the end of spring 2022 with 8 of the 10 enrolled students. The discussion was audio-recorded and professionally transcribed, and a coding directory was created using the focus group questions. The transcript was coded to identify primary thematic areas, and the data were entered into Dedoose to facilitate thematic analysis [8]. The evaluation protocol was submitted to and granted exempt status by the University of Delaware IRB. The themes that emerged from the qualitative data are summarized below.

Course Structure: Overwhelmingly, students viewed the course favorably. They found the non-traditional course structure highly interactive and engaging. Students identified the guest speakers as what they liked best, as the speakers exposed them to aspects of the BME profession they had not considered. The course structure, in particular the approach to teaching CAD, helped students learn the required course material. Students would have liked more opportunities for CAD and hands-on, physical design. Students' expectations about the course based on the course title and the actual content were not always aligned. As explained by a student:

> *"When I heard design, I was like, 'Oh, like building CAD' which was incorporated into the class. I think in my mind going into it, I definitely didn't think there'd be as much focus on the regulatory pathways as it was."*

This quote exemplifies students' misconceptions that design entails only CAD and prototyping. Our course, and the exposure students receive to different medical device industry roles, attempts to ameliorate this limited belief, broadening students' future career path options.

Students felt the three selected medical device units (surgical staplers, breast pumps, and stents) allowed them to achieve the course goals. For example:

> *"Overall, the projects definitely did a good job at accomplishing the course goals because they were so inclusive of everything we'd been working on and learning. I did appreciate that all the devices were very unique from each other. You went about each of the tasks in a different way depending on which device you were working on."*

However, the students recommended changing stents for another device because they did not feel there was much to stents mechanically or for customer input. In the future, greater emphasis on engineering considerations of stents, such as biocompatibility and materials, could be introduced.

VoC Videos: For the most part, students found the VoC videos informative and insightful. In addition, the interview transcripts helped students review for understanding and easily pull quotes when needed. As one student explained:

> *"I found the breast pumps* [video interviews] *definitely to be the most useful because they had a lot of personality to what they wanted to say about the product. Whereas the stents, the doctors were implementing them, and the consumer had pretty much no say. 'The doctor thinks it's best.' I also did like the surgical staplers. How a lot of the doctors, especially the ones, they were talking about how they had smaller hand sizes. So, it was harder for them to hold the stapler, which I think we did that for our needs statement on the first project."*

This quote suggests that capturing diverse viewpoints makes for impactful VoC videos. We intend to evaluate the impact of these VoC videos more deeply in the future.

Teamwork: For the most part, students enjoyed working in teams. They liked that their teams were formed via CATME, a validated online tool for team-formation and peer evaluation [9, 10], and they found it helpful to identify their strengths and weaknesses and to divide tasks based on defined roles. For the most part, students thought the group sizes (3-4) worked well as they allowed everyone to take on a specific job as if they were in the workplace. For example:

> *"[We] did have our distinct roles, like regulatory, CAD, that side and project manager. We still helped each other out. We had to. We also split up the documents, we put our names, we all worked on the document together. Just had different roles in those documents."*

We have planned assessments for the future to evaluate the impact of the simulated team roles.

Future Aspirations: Lastly, students were asked if they saw themselves becoming a biomedical engineer in the future. Although most students were not sure if they would enter the field of biomedical engineering, they were confident that they would graduate with their BME degree. We are collecting ongoing data about students' BME professional identity and career aspirations.

Conclusion and Path Forward

The first implementation of BMEG260: Introduction to Medical Device Design affirmed the course structure and the benefits of the selected medical devices, video interviews, teamwork, and guest speakers. Future iterations of the course will scale to the entire sophomore cohort and periodically introduce new medical device units. To effectively scale, we need multiple studio sections (3 for a cohort size of 50-60 students) and teaching assistants to help with course management and grading. The benefit of the course structure is that the VoC videos, guest speakers, and SolidWorks video lessons are all inherently scalable. Evaluation, through surveys based on validated instruments [11]-[14], focus groups, and direct assessments, is ongoing to assess BME identity, career path and future aspirations, the impact of team roles, self-efficacy for teamwork and engineering design process skills, and the impact of the voice of the customer videos. Longitudinal assessments and comparisons between cohorts will provide information on the impact of the course. In conclusion, this new, sophomore-level medical devices course is addressing gaps in the biomedical engineering undergraduate curriculum.

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Appendix A: BMEG260 Course Learning Goals

1. Deconstruct how the **engineering design process** applied in the development of existing medical devices
    a. Write a need statement that identifies the problem, population, and desired outcome
    b. Develop design inputs that
        i. Are justified
        ii. Can be verified and validated
        iii. Apply the voice of the customer
        iv. Consider public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors
        v. Apply relevant engineering standard(s), including FDA Recognized Consensus Standards
    c. Identify and benchmark potential competitor and predicate devices
    d. Find and interpret relevant patents
    e. Explain how existing medical devices work by justifying key design decisions
    f. Create a FMEA table to consider and prioritize potential device failure modes, effects, and causes
2. Create **dimensioned models** of medical devices by using computer-aided design
    a. Use digital calipers to measure dimensions of devices
    b. Create models of devices by using intermediate solid model operations in SolidWorks
    c. Create assemblies of devices in SolidWorks
    d. Perform basic measurement evaluations on SolidWorks models
    e. Read and interpret basic engineering drawings
3. Explain **U.S. regulatory requirements** to market different FDA classes of medical devices
    a. Explain the US Quality System Regulations for medical devices, 21 CFR Part 820
    b. Use the FDA Product Classification Database to classify medical devices as class I, II, or III
    c. Distinguish and explain the different FDA approval pathways for new medical devices (Exempt, Premarket notification 510(k), De novo, Premarket approval (PMA), Humanitarian devices (HDE))
    d. Use the FDA MAUDE database to identify potential modes and causes of failure
    e. Develop and maintain a Design History File (DHF) for project documentation
4. Recognize **ethical and professional responsibilities** in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts
    a. Consider the impact of medical devices in global, economic, environmental, and societal contexts
    b. Apply codes of ethics
    c. Describe ethical considerations in research and clinical trials
    d. Outline steps for ethical engineering decision-making
5. **Function effectively on a team** whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives
    a. Create a project timeline
    b. Write meeting agendas and notes
    c. Assign and document team member roles and tasks
    d. Create SMART goals
6. Simulate different examples of **roles and tasks in the medical devices industry** (e.g., Design engineer, Regulatory affairs, Quality assurance, Marketing & sales, New Product Development Systems Engineer)

Appendix B: Focus Group Discussion Questions

A comprehensive evaluation plan, in alignment with the standards established by the Joint Committee on Standards for Education Evaluation [15] and the American Evaluation Association's Guiding Principles for Evaluators [16], was prepared by a professional evaluation team, in collaboration with the course instructor/principal investigator. This evaluation plan included a focus group and formative and summative components. The evaluation team employed a theory-based, participative approach to evaluation. Evaluation questions were designed for each component. An element of the formative evaluation sought to answer the following questions: "What elements of the program are useful or not useful? What are the program's strengths and weaknesses? What programmatic elements could be improved?" The summative evaluation sought to determine to what extent the program impacted participant knowledge and skills in biomedical engineering and their aspirations and preparation for a career in biomedical engineering. The evaluation team developed the focus group questions to answer these questions. The developed questions were then discussed with the course instructor/principal investigator and revised to incorporate the feedback received. The final focus group script is provided below.

About the Course

- What did you like best about the course?
- What helped you the most to learn the required material?
  Probe: Clinician/patient Videos, working in teams, guest speakers, hands-on device dissections, mixed instructional approach
- What would you change about the course?
- What would you make sure wasn't changed about the course?
- How did the 3 selected medical device units – Surgical staplers, Breast pumps, and Stents impact your achievement of the course goals?

Course Goals

- Deconstruct how the engineering design process is applied in the development of existing medical devices, with an emphasis on applying the voice of the customer
- Create dimensioned models of medical devices by using computer-aided design
- Explain U.S. regulatory requirements to market different FDA classes of medical devices
- Recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts

How did these units support the course goals and similarities/differences in their ability to support the goals?

Working in Teams

- What element(s) of working as a team did you find useful? Why
  Probe: defining, assigning, and rotating industry-based job titles and responsibilities
- What element(s) of working as a team did you find not useful? Why
  Probe: defining, assigning, and rotating industry-based job titles and responsibilities
- How did your teamwork experience in this course impact your development of industry-relevant skills?
- How did your teamwork experience in this course impact your ability to identify career pathway options for a biomedical engineer working in the medical devices industry?
- What (if anything) would you change about the teamwork aspect of the course?
- What would you make sure wasn't changed?

Course Tools

There were tools used to support your learning in the course to include (a) clinician/patient videos, (b) guest speakers, and (c) hands-on device dissections. I would like to hear your feedback on each of these.

- What were the most important things you learned/took away from each tool?
  Probe: How/did the voice of the customer videos help you understand the clinical context and identify unmet needs of existing devices?
- What did you find useful/helpful?
- What (if anything) was not useful/helpful?
- What suggestions can you provide for improvements?

Engineering Identity/Sense of Belonging

Students in engineering programs for various reasons do not see themselves as engineers.

- Do you see yourself as becoming a Biomedical engineer? If so, why? If not, why?

Probes:

- *What characteristics or skills do you have that you think will help you as an engineer?*
- *What (if any) characteristics or skills will keep you from becoming an engineer?*
- *How did your participation in this course impact how you see yourself as a biomedical engineer?*

Wrap-Up

- Is there anything you learned during the course that you were not expecting?
- Is there anything else we didn't discuss about your experience this semester that you would like to mention now?
- Any additional suggestions you can provide for course improvements?