Work in Progress: Healthcare Economics and Information Literacy - Resources for Success in Undergraduate Biomedical Engineering Education

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Andrew started in the NYC Motion Picture Industry before transitioning into his 15+ years in Biomedical Product Development. Today he teaches design and innovation in Biomedical Engineering (BME) at UNC & NC State where he is an Associate Professor of the Practice. His students' coursework led to multiple startups including Novocor Medical Systems, Augment Medical, Contour Surgical, 410 Medical, and MEDIC. He is founder and former executive director of the NC Medical Device Organization, which became an ncbiotech.org Center of Innovation. He was co-founder and VP Business Development for the design and manufacturing company EG-Gilero. Andrew worked for Alaris Medical Systems (now BD's CareFusion) as a design engineer and project manager. He is Business Advisor and Speaker for the Wallace H. Coulter Foundation, an advisor to the NIH C3i Program, Director of Duke NeuroInnovations, and on the planning team for BME IDEA. He holds a BS in Physics, English Literature, and Secondary Education from UNC Charlotte, an MS in BME from UNC Chapel Hill's Medical School, and a Ph.D. from the UNC/NCSU BME Department.

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Kelly Umstead is an assistant professor of industrial design at North Carolina State University. She earned her MID from NC State University and her MS in biomedical engineering from Marquette University. Umstead's professional experience is rooted in research, beginning as an engineer with a focus on biomechanics and human movement with applications ranging from gait analysis and rehabilitation to sports science and aquatics. As an industrial designer, she specialized in medical device design and product usability. Umstead is the chair of the Industrial Designers Society of America's Medical Special Interest Section. At NC State University, her research interests include healthcare, medical device development, user-centered design and design research methodologies.

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The pathway to successful medical innovation includes a labyrinth of business hurdles including regulatory approval, reimbursement strategy, intellectual property, and marketing challenges [1]. Early consideration of these factors informs critical decisions in the biomedical engineering (BME) design process that minimize product and business risks. Information literacy training provides students with strategies for discovering the wide range of resources for biomedical engineering design. This expanded knowledge base can be leveraged to generate more fully realized solutions that may improve commercialization success and decrease time to market, ensuring the medical innovations more quickly reach patients and healthcare providers.

This poster and extended abstract present the preliminary results of a second cohort of BME students who are matriculating through an expanded information literacy program. This updated information literacy curriculum, implemented in two phases over two academic years, exposes students to the complex environment surrounding innovative design in healthcare broadly, and medical device design in particular [2]. This additional component of the design project requires BME students to consult and cite a diverse array of information sources within their project documentation, including patents, business intelligence, legal proceedings, FDA regulatory information, as well as insurance reimbursement and medical bill coding.

Methodology

To evaluate the effectiveness of this updated curriculum, we are conducting a three-arm cohort study, which evaluates the outcomes of student teams that have matriculated through NC State University's undergraduate BME program. The students from each of the cohorts worked together in project teams of approximately 7 students on average. The first arm, which serves as a control group for the study, was drawn from a representative sample of student assignments completed prior to the implementation of the updated information literacy training program. The second and third arms of the study, referred to as Phase I and Phase II, include a sample of student teams from the BME Class of 2017 (Phase I) and the BME Class of 2018 (Phase II).

Phase I of the study presented students with information via a single engineering librarian guest lecture during their junior and senior design courses. During the junior level lecture, students were trained on finding: epidemiology data and disease state information, peer-reviewed articles from scholarly journals, patents, and business intelligence information on competitor medical device companies. The senior level training introduced students to additional sources specifically relevant for medical device development, including: standards, legal information, FDA regulatory information, and reimbursement and medical billing information. A noteworthy limitation of our Phase I implementation of this training was that it was provided via lecture, which severely limited the amount of time students had for demonstrations, explorations, and guided practice in utilizing these new tools while with a librarian. In Phase II, the instruction within the senior design course was delivered via a low enrollment, four hour lab class. This change enabled the instructors to develop a highly interactive lecture that featured active learning activities. These activities increased hands-on, guided practice time with these concepts, and allowed librarians to address misunderstandings early in the design process.

The impact of this curriculum on student learning is being assessed by the project team, which includes both librarians and the instructors of record for this course, using three different methods. First, student participation in engineering design competitions was tracked, which serves as a metric for evaluating students' self-confidence in their projects. Additionally, student achievement of four learning outcomes, created using the National Institute of Biomedical Imaging and Bioengineering (NIBIB) / VentureWell Design by Biomedical Undergraduate Teams (DEBUT) challenge, was assessed using rubrics (see Table I) [3], [4]. Lastly, the students' citation patterns in their final assignments were analyzed.

Table I: Evaluation Criteria

Criteria 1	Justify the problem addressed by explaining the impact on potential users and clinical care
Criteria 2	Evaluate design concepts for market potential, economic feasibility, and patentability
Criteria 3	Design the product as a creative response to a need, the functionality of which is driven by people
Criteria 4	Apply engineering knowledge and skills to build a working prototype

Preliminary Results

Dispersing instruction across two semesters enabled instructors to provide students with more healthcare specific information resources, and our preliminary results show some promising positive effects. Using a paired, two-tailed t-Test, we found that the average scores for student teams from Phase I showed statistically significantly improvement over average scores for student teams in the control group ($p = 0.0075$) when measured across all four learning outcomes (see Figure 1). Furthermore, Phase I teams entered more design competitions, both at the local and national level, than control group teams (see Table II). However, we did not see any meaningful difference between the citation patterns of control group teams and teams in Phase I.

Figure I: Student Achievement of Learning Outcomes

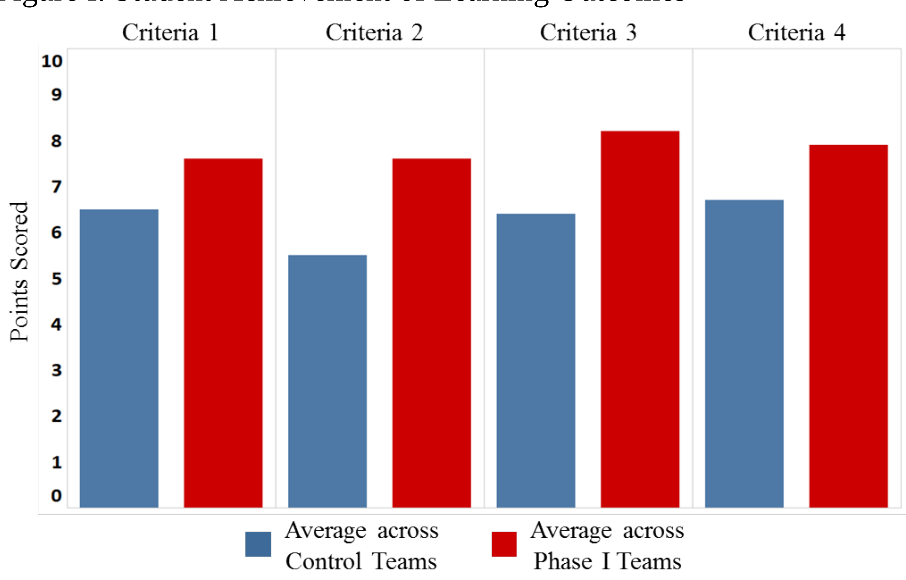

Table II: Student Design Competition Participation Rates

Cohort	Year	Total Entries	Teams Participating	Participation Rate	National Contest Entries	Local Contest Entries
Control (n = 72)	Average, (2010-2016)	6.3	4.3	42.6%	4.5	1.9
Phase I (n = 12)	2017	15	6	50.0%	7	8
Phase II (n = TBD)	2018	TBD	TBD	TBD	TBD	TBD

Table III: Table 4: Citing Information Sources

Cohort	Average Number of Sources Cited	Lowest Number of Sources Cited	Highest Number of Sources Cited	Range
Control (n = 5)	8	1	14	13
Phase I (n = 5)	7.8	0	22	22
Phase II (n = TBD)	TBD	TBD	TBD	TBD

Because of this change in instructional design, we hypothesize that students engaged in Phase II training will participate in more engineering design competitions and achieve higher scores in all four learning outcomes than students in Phase I or in the control group. Our research protocol, as approved by our Institutional Review Broad, prohibits us from analyzing student learning results prior to each cohort's graduation, so we are unable to share data from Phase II at this time.

Conclusion

The accompanying poster for this extended abstract will share the results from Phase II and compare these data with control and Phase I data. Our poster will close with lessons learned from this multi-year collaboration between an engineering department and a university library, and practical suggestions for how others in the field may use similar strategies for supporting students in the areas of medical device design and innovation.

References

[1] T. K. Grose, "Invention Roulette," *ASEE Prism*, vol. 26, no. 1, pp. 36–39, 2016.

[2] A. J. Carroll, A. J. DiMeo Sr., H. O. Ozturk, and J. McCall, "Work in Progress: Integrating Medical Economic Perspectives through Information Literacy in a Biomedical Clinical Immersion Design Course," presented at the 2017 ASEE Annual Conference & Exposition, 2017.

[3] VentureWell, "DEBUT competition guidelines," *VentureWell*, 21-Jan-2015. [Online]. Available: https://venturewell.org/guidelines/. [Accessed: 18-Oct-2017].

[4] National Institutes of Health, "Design by Biomedical Undergraduate Teams (DEBUT) Challenge," *National Institute of Biomedical Imaging and Bioengineering*, 22-May-2013. [Online]. Available: https://www.nibib.nih.gov/training-careers/undergraduate-graduate/design-biomedical-undergraduate-teams-debut-challenge. [Accessed: 17-Mar-2017].