Integrating Medical Economic Perspectives through Information Literacy in a Biomedical Clinical Immersion Design Course (Work in Progress)

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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 product innovation in Biomedical Engineering (BME) at UNC & NC State where he is an Associate Professor. Andrew's courses resulted in multiple startups including Novocor Medical Systems, Augment Medical, Contour Surgical, 410 Medical, and MEDIC. He is founder and former director of the NC Medical Device Organization, which became an NC Biotech Center of Innovation. He was co-founder and VP Business Development for Gilero, an RTP based service company. 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, 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. Andrew has two children, 15-year-old daughter Virginia Elaine and 13-year-old son Andrew, Jr. His wife, Abigail Kent, is a nurse at the NC State Highway Patrol.

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Works in Progress: Integrating Clinical and Entrepreneurial Information Literacy into the Biomedical Engineering Design Curriculum

The landscape of today's Biomedical Product Development Industry calls for a diverse set of skills beyond the typical engineering fundamentals. The current Hospital Value-Based Purchasing environment driven by the Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS) measure all new products by their ability to improve clinical outcomes, increase patient satisfaction, and lower the cost of care.[1] Preparing students to become leaders in the Biomedical Engineering (BME) industry therefore must include an understanding of health economics and a broad view of the continuum of care and overall impact of care. The proposed changes to Accreditation Board for Engineering and Technology, Inc.'s (ABET) Criterion 3 signals the changing demands of the modern medical device product development environment. Under the proposed changes, accredited BME programs will be expected to develop diverse teams of engineers that are not only comfortable in the clinical environment, but also "recognize ethical and professional responsibilities in engineering situations" and have the ability to identify "the ongoing need for additional knowledge and locate, evaluate, integrate, and apply this knowledge appropriately."[2]

For many engineering disciplines, teaching students how to find and use journal articles, patents, and standards ensures that they will have a relatively complete understanding of the professional information environment.[3] However, BME students entering the workforce increasingly need to be well versed in finding and utilizing additional sources of information, such as clinical data and medical bill coding.[4] Recognizing this gap in the curriculum, in the spring of 2016 several instructors from the North Carolina State University Department of Biomedical Engineering began partnering with the North Carolina State University Libraries to implement a substantially more rigorous information literacy training program. In this overhauled instructional design, students now receive training during their junior design course on finding: epidemiology data and disease state information; peer-reviewed articles from scholarly journals; patents; and business intelligence information on competitor medical device companies. During their senior design course, students receive training on finding: standards; legal information; FDA regulatory information; and reimbursement and medical billing information. This training is delivered via guest lectures from an engineering librarian, who in addition to explaining how and where to find these types of information also teaches students how to use information ethically. Students receiving this updated information literacy training are required in the documentation that accompanies their design projects to include relevant information from these different data sources, and to synthesize the information they find to justify the potential marketability of their product while considering CMS value-based criteria.

Course Descriptions

BME 352 (Junior Design) is a one-semester required course and prerequisite to Senior Design. The course is split between hands on manufacturing skills and product development skills to prepare students for Senior Design. Topics covered in Junior Design include lab safety, keeping a scientific notebook, need statement development, problem identification, needs filtering, product validation, product specifications, brainstorming, introduction to hospital shadowing,

working in teams, design for manufacturing, document controls, market analysis, intellectual property basics, library skills, regulatory basics, healthcare economics, and project management.

BME 451 and 452 (Senior Design) is a two-semester required course to prepare students for the workplace and/or graduate studies. The course uses a Design Control Process based on the FDA's Quality System Regulations to move student teams from a Needs Assessment through Product Development and Testing. Each team progresses through a minimum of 4 phases while maintaining a Design History File. The aim of the courses is to provide the opportunity for senior biomedical engineering students to both integrate and continue to grow their engineering knowledge by accomplishing "real world" engineering design projects. In addition to project activity, students are provided educational resources addressing ethics and professionalism, manufacturing and standards, and intellectual property. BME 451 encompasses the Project Proposal and Design Concepts, including: individual pre-proposals, team proposals, project planning, scheduling, needs assessment, product requirements, competitive landscape and patent review, business risks, design concepts, and phase reviews. BME 452 is a continuation of BME 451 moving from Proposal and Concepts into Manufacturing, Prototyping, and Testing. The deliverables in this course include: detailed manufacturing specifications, biomaterials review, supplier identification, product feasibility, issues tracking, manufacturing planning, bill of materials, product risks, qualification protocol, IP disclosure, process validation planning, regulatory review, design history file audit, lessons learned, and phase reviews.

Methodology

To measure the effects of the updated information literacy training for these courses, the investigators are conducting a cohort study. Our control group is drawn from a representative sample of student assignments that were completed prior to the implementation of the updated information literacy training program. While students in the control group received a single lecture on finding articles and patents during BME 451, they did not receive training on how to find hospital-based value purchasing information. We define these types of sources as including, but not limited to: CMS coverage, Current Procedural Terminology (CPT) codes, 510(k)s, FDA Premarket Approvals and Post-Approval Studies, product recalls, and medical device litigation, among others. Students in Experimental Group One (EX1) are drawn from a representative sample from the BME Class of 2017. Students in EX1 received training on finding articles and patents during their junior design course (BME 352), as well as specific training on how to find hospital-based value purchasing information during their senior design course (BME 451). However, students in EX1 were not required to use this information in any assignments. Students in Experimental Group Two (EX2) are drawn from a representative sample from the BME Class of 2018. Students in EX2 received the same training as students in EX1; however, their assignments explicitly require them to utilize the information sources they are being introduced to in these training interventions. Students in EX2 will also be required to send a member of their design team to meet with a librarian to discuss their information seeking strategies, as well as any barriers they are encountering during this process.

We hypothesize that increasing the extent and frequency of instructional interventions on information seeking will increase the quality and variety of information that students consult during their design projects. We further hypothesize that the students' extent of information use

will correlate with overall success of the design project. Lastly, to determine whether or not instructor requirements were more determinative than the instructional intervention, we updated some of the assignments to explicitly require the EX2 cohort to use hospital-based value purchasing information sources. Table 1 presents a visual breakdown that explains the training and assignment differences between the groups.

Table 1. Cohort Descriptions

Cohort Title	BME 352 Intervention?	BME 451 Intervention?	Info Use Requirements	Required Meeting with Librarian
Control	No	Yes	No	No
EX1	Yes	Yes	No	No
EX2	Yes	Yes	Yes	Yes

To assess the effectiveness of this new instructional intervention, rubrics (see Appendix A-D) are being used to measure several aspects of students' utilization of information in their documentation, such as the extent of information use, selection of appropriate resources, ethical use of information, and the effectiveness of use, among others. Performance in information use, as measured by rubrics, will be correlated with the grade student teams received on their overall design project to determine if a relationship exists between extent of information use and overall performance. Other outcomes of interest that will be used as points of comparison between the groups will include design competition participation rates, performance in end of semester presentations, as well as compliance with assigned deadlines for project components. For example, we will measure teams' participation rate in the DEBUT challenge.[5] The control cohort had a participation rate of approximately 8 percent (n=12), which will be used as a baseline for comparison for each experimental group. In addition to tracking participation rate, we will compare each cohort's contest submissions by measuring their projects' achievement of the following learning outcomes: 1) justify the problem addressed by explaining the impact on potential users and clinical care; 2) evaluate the design concepts for market potential, economic feasibility, and patentability; 3) design the product as a creative response to a need, the functionality of which is driven by people; 4) apply engineering knowledge and skills to build a working prototype.

Conclusion

Our 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 our preliminary data at this time. The accompanying poster will share the authors' preliminary findings based on the results from the control group as well as EX1. It will also discuss lessons learned from this long-term collaboration between an engineering department and a university library.

Appendix A: BME 352 EX 1 Relevant Research Rubric

Use of Deliverable Format (Max 10pts) - Names and Dates Included - Signature Blocks - Revision Table - Heading Styles	
Content (Max 80pts) Required: - Define the need and problem being addressed - Relevant research of your need including at least 5 in text citations - Competitive Landscape of 5 products addressing your need - Patent Landscape of 5 products addressing your need - Include a complete bibliography with formal citations in the style of your team's choosing citing **ALL** resources used (including those used for competitive and patent landscape). - Brief justification for your citation style used (2-3 sentences)	
Quality of Work (Max 10pts) - Thorough analysis of your need. - Detailed descriptions of competitors and patents - All citations are properly formatted	

Appendix B: BME 352 EX 2 Relevant Research Rubric

Use of Deliverable Format (Max 10pts) - Names and Dates Included - Signature Blocks - Revision Table - Heading Styles	

Content (Max 80pts)
 	
Required:
- A narrative introduction that define the need and problem being addressed
- Brief justification for your citation style used (2-3 sentences)
- A complete annotated bibliography with at least 10 formal citations in the style of your team's choosing citing **ALL** resources used.
- Each annotation includes:
    o What type of source it is (epidemiological information, journal article, patent, or company information).
    o Where you found the source (i.e., database searched).
    o A one sentence summary of the information contained in the source.
    o A one sentence explanation of relevance of the information to your device.
- Of the 10 sources cited in the annotated bibliography, one must be epidemiological information, two journal articles, two company profiles / business information, two patents, and three of your choice	

Quality of Work (Max 10pts) - Thorough analysis of your need. - Detailed descriptions of competitors and patents - All citations are properly formatted	

Appendix C: BME 451 EX 1 Competitive Landscape and Patent Review Rubric

Category	Points	Grade
Quality of Work	25	

Content
 	
    ◆ All sections of the deliverable have been adequately filled out:
        ◆ Abstract
        ◆ Industry Environment
            ◆ Define the industry sector for the product
    ● Competitor Profiles
        ◆ List and describe other companies in the sector
        ◆ Justify if companies are a potential competitor, partner or both
        ◆ Product Landscape
            ◆ List all competing or similar products and a short description
            ◆ Note the shortcomings of each product and how yours will address it
            ◆ Pictures of competing products (or provided in Appendix)
        ◆ Customers of Competitor
        ◆ Patent Review
            ◆ List all existing patents applicable to work
            ◆ Give a brief description of patents most relevant
        ◆ Relevant Research
            ◆ Discuss relevant research being conducted in the product sector
        ◆ References/Appendices
            ◆ Pictures of competing products (or provided in Product Landscape section)
            ◆ Links to other companies
	65	

Formatting
 	
    ◆ Filename follows format: <T##-D13-Comp-and-IP-Landscape.pdf>
    ◆ Deleting highlighted areas
    ◆ Single Spaced, 1" Margins, 12-point Times New Roman font
    ◆ Proper placement of name or date locations
    ◆ Table of Contents reflects section names and page numbers
    ◆ No sponsor signature
    ◆ Spelling/grammar
	10	

Appendix D: BME 451 EX 2 Competitive Landscape and Patent Review Rubric

Category	Points	Grade
Quality of Work	25	

Content
 	
    ◆ All sections of the deliverable have been adequately filled out:
        ◆ Abstract
        ◆ Industry Environment
            ◆ Define the industry sector for the product
    • Competitor Profiles
        ◆ List and describe other companies in the sector
        ◆ Justify if companies are a potential competitor, partner or both
        ◆ Product Landscape
            ◆ List all competing or similar products and a short description
            ◆ Note the shortcomings of each product and how yours will address it
            ◆ Pictures of competing products (or provided in Appendix)
        ◆ Customers of Competitor
        ◆ Patent Review
            ◆ List all existing patents applicable to work
            ◆ Give a brief description of patents most relevant
        ◆ Relevant Research
            ◆ Discuss relevant research being conducted in the product sector
        ◆ FDA Medical Device Review
            ◆ Discuss relevant products previously reviewed, approved, or recalled by the FDA (510(k)s, Premarket Approvals, Post-Approval Studies)
        ◆ References/Appendices
            ◆ Pictures of competing products (or provided in Product Landscape section)
            ◆ Links to other companies
            ◆ Documented meeting with Research Librarian
	65	

Formatting
 	
    ◆ Filename follows format: <T##-D13-Comp-and-IP-Landscape.pdf>
    ◆ Deleting highlighted areas
    ◆ Single Spaced, 1" Margins, 12-point Times New Roman font
    ◆ Proper placement of name or date locations
    ◆ Table of Contents reflects section names and page numbers
    ◆ No sponsor signature
    ◆ Spelling/grammar
	10	

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