CREATION OF A BIOETHICS COURSE FOR THE UNDERGRADUATE BIOMEDICAL ENGINEERING CURRICULUM

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Abstract

"Engineering programs must demonstrate that their graduates have...an understanding of professional and ethical responsibility....¹" To address this need, we are creating an undergraduate biomedical engineering (BME) ethics course, which serves to raise awareness in students and better prepare them for careers in medicine, research, and engineering. The principles and methodologies of the course are centered around the Legacy learning cycle² used by the VaNTH Engineering Research Center, in accord with learning principles addressed in How People Learn³. Students' awareness of professional and ethical issues are increased through the investigation of ten to twelve case studies with in-class discussion, in-class movies with pre and post discussion, and guest speakers. Investigation of cases include documentation of students' initial thoughts on issues, then systematic reflection on these thoughts through introduction of multiple perspectives provided by guest lectures, thought papers and in-class discussions. Case studies cover a wide variety of application areas, including genetic engineering, xenotransplantation, using animals in research, rights of patients and research subjects, and BME technology development. Media depictions suggesting ethical issues are alternative presentation modalities allowing students to develop awareness of purposes and viewpoints of authors as well as subjects covered. Guest speakers serve as experts on ethical issues in areas of biomedical and clinical research, clinical medicine, and biotechnology and also serve as resources for students in developing their own solutions to ethical problems. Students bring background knowledge and personal beliefs to the classroom, and in-class discussions and reference materials provide students with multiple perspectives on bioethics problems. Our expectation is that students will leave this course with broader perspectives, and increased ability to discern and make judgments on ethical issues in biomedical engineering, medicine, and clinical research.

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Introduction

According to the ABET accreditation cycle, "engineering programs must demonstrate that their graduates have...an understanding of professional and ethical responsibility.¹" Currently, the Department of Biomedical Engineering at Vanderbilt University does not include an explicit ethics component in the curriculum for undergraduate students. To address this need, we are creating an undergraduate biomedical engineering (BME) ethics course, which will raise awareness in students and better prepare them for future careers in bioengineering, clinical medicine, and biomedical research.

Since many BME students will enter careers in fields other than biomedical engineering, it is important to develop a clear and distinct definition of bioethics for biomedical engineering. Upon graduation, about a third of students typically enter careers in biomedical engineering or other engineering related fields, another third will enter advanced studies in BME or other disciplines, and another third will enter medical school or other clinical medicine fields. Topics and case studies that represent these fields of study must be chosen to help students develop a clear definition of bioethics and a clearer understanding of ethical concepts in biomedical engineering today. Providing a course that focuses on the ethical aspects of biomedical engineering will help students gain a fundamental sensitivity to human life such that they are able to assess the importance of human life in medicine, research, and engineering problems.

Goals and Objectives

The learning principles and methodologies of the course are centered on the Legacy learning cycle² used by the VaNTH Engineering Research Center, in accordance with the learning

principles addressed in How People Learn³. The HPL model integrates four primary learning foci (Figure 1). Knowledge centeredness refers to the new information that students will encounter in the course. The course instructor has the primary responsibility in this area. Accurate and adequate amounts of information must be made available to students in a way that stimulates their interest and builds on information and ideas that they bring to the learning experience. Learner centeredness represents the focus on the learner and the learning process. Learners are encouraged and led to learn with understanding, not just memorize facts and concepts. Students come from a wide variety of educational and moral/ethical backgrounds. Expression of divergent views

How People Learn



Figure 1. HPL Model: Student Learning Environment

can provide new information and increased understanding for other students, and also provide a basis for the third focus, that of assessment, both formative (helping the learner to evaluate his/her own progress) and summative (allowing the instructor to evaluate the learner's progress). The

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fourth focus of the learning method is that of community. The learning environment is a community in which learning is optimized through exchange and refinement of ideas. The ideas also represent personal and professional practice in community.

The Legacy learning cycle models the process of solving engineering problems, and can be applied to solving problems in biomedical engineering ethics. Ethical case studies are presented to students as an engineering challenge. Students first generate ideas about the problem based on their own background information about the topic. Next, students gain insight into the problem through exposure to multiple perspectives. Classroom discussions provide insight into the knowledge and opinions of the peer group, and guest speakers provide expert advice on the topic. Then, students must research and revise their original ideas with information in published journals, textbooks, websites and other sources. Next, students test their new theories or solutions in a discussion setting, and finally present a reasonable solution to the problem to the class and/or instructor for evaluation.



Figure 2. Legacy Learning Cycle

Materials and Methods

The primary goal in creating the bioethics course is to design a course methodology in which the concepts compliment theory and principles learned during earlier courses in undergraduate biomedical engineering. In order to accomplish this goal, it is necessary to invoke multiple perspectives from a wide variety of sources, including biomedical engineering students and faculty and bioethics faculty. Professors from the Departments of Biomedical Engineering and Philosophy and the Center for Research and Clinical Ethics were interviewed to get ideas for case studies and course content.

Biomedical engineering students were observed and interviewed in a variety of settings. Students in a second-year biomedical engineering thermodynamics class were placed into groups and instructed to research the topic "Embryonic Stem Cell Research." Each group advocated the points of view of groups and institutions such as the FDA, the NIH, businesses, etc. The groups presented their points of view to the class, and an open discussion was conducted to evaluate the different perspectives. A similar assignment was given to senior students in a BME biotechnology class. Students were divided up into teams and given topics of current interest in biotechnology such as the use of artificial organs, embryonic stem cell research, etc. Two teams were assigned per topic (one pro, one con), and each team was instructed to research the given point of view and prepare an oral presentation. Teams defended their cases in debate form, and classmates voted on the winner of the debate.

Some background information for course content comes from a study by the VaNTH ERC

entitled "BME Goes to the Movies." Brophy et al. explored the use of movies as a vehicle for identifying and refining understanding of ethical issues in a case⁴. Undergraduate students were given the option to view the film *Miss Evers' Boys*, a dramatization of the Tuskegee Study on syphilis from 1932 to 1972. Students were given a short questionnaire which pre-assessed their background knowledge about the case and research using human subjects. After viewing the movie, students filled out the same questionnaire, and an open discussion was conducted to view multiple perspectives. Most students responded positively to the use of movies as a tool for introducing ethical concepts, and the comparison of pre- and post-questionnaire positions indicates an increased awareness of issues in clinical research ideas after viewing the film⁴.

We attempted to create a backbone for the course structure by looking at existing bioethics courses at various universities. Some course descriptions were available online at Johns Hopkins University, University of Pennsylvania, Georgetown University, University of Virginia, and Vanderbilt University. We observed the undergraduate philosophy course, Introduction to Ethics, at Vanderbilt University and interviewed engineering students enrolled in the course.

Further ideas for case studies and course content were supplemented by web research from various institutions. The World Medical Association⁵ provided us with historical documents such as the Declaration of Helsinki, Belmont Report, Nuremberg Code, etc. The Bioethics Resource Center from the National Institutes of Health⁶ provided us with additional documents and case studies. The Case Studies in Science website⁷ from the University of Buffalo provided us with the bulk of case studies used in the syllabus.

Results

We successfully created a day-by-day semester course syllabus (presented below for fall 2003 dates). The course includes thirteen case studies, four guest speakers, three in-class movies, and a group project.

Ethics in Biomedical Engineering Course Syllabus

- August 28 Overview of syllabus; Guest speaker on bioethics
- September 2 In-class video *Miss Evers' Boys;* Introduction to the Tuskegee study and a brief history before viewing the movie; Pre-questionnaire administered before viewing the movie
- September 4 In-class video Miss Evers' Boys; Post-questionnaire after movie; Open discussion
- September 9 Laws and regulations created in the 20th century
- September 11 Ethical institutions: government, private, etc.
- September 16 Case Study: Embryonic vs. Adult-stem cell research
- September 18 Case Study: Embryonic Stem-Cell Research Moral issues

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September 23 – Guest speaker on ethics in biomedical technology (BME department)

- September 25 Case study: Transmyocardial revascularization
- September 30 Case study: Biomedical technology VeriChip
- October 2 Design of an analytical thought process that incorporates ethical considerations into BME design
- October 7 Introduction to team project, assign teams and topics, Introduction to genetics research, view segments of *Cracking the Code of Life*
- October 9 Case study: Who owns the human genome? Race to decode the human genome
- October 14 Case study: Humans as "virtual subjects" for gene therapy research; Iceland DNA database
- October 16 In-class or take home midterm
- October 21 Fall Break
- October 23 Guest speaker on artificial organs (VUMC or VUH)
- October 28 Case study: Xenotransplantations and artificial organs?
- October 30 Case study: Who's responsible when medical treatment becomes harmful? Peanut Allergy Case
- November 4 Guest Speaker on Biomedical Research (VUMC or VUH)
- November 6 Case Study: How important is the life of the human subject? Muscular Dystrophy study using human subjects
- November 11 Case study on animal research
- November 13 In class movie: A Right to Die? The Dax Cowart Case
- November 18 Case Study: Right to refuse medical treatment Dax Cowart Case
- November 20 Case Study: Informed consent with people who can't decide for themselves (infants, children, senior citizens, mentally ill) Scoliosis Case

November 25/27 – Thanksgiving Holidays

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- December 2 Case Study: Informed consent with people who can't decide for themselves (infants, children, senior citizens, mentally ill) Prisoner Case
- December 4 Project Presentations
- December 9 Project Presentations
- December 11 Last day of class; Evaluations

Discussion

We included case studies that are both historically and currently significant to biomedical engineers today. We considered the fact that BME students will enter a variety of fields upon graduation including engineering/biotechnology, clinical medicine, and medical research. To accommodate for these career goals, we selected cases relative to these three fields of study. Case studies that focus on clinical medicine include the peanut allergy case, muscular dystrophy study, Dax Cowart case, and two informed consent cases. Case studies that focus on medical research include embryonic/adult stem cell research, human genome project, Iceland DNA database, muscular dystrophy study, and animals in research. Case studies that relate directly to the field of biomedical engineering and biotechnology are transmyocardial revascularization, VeriChip, and artificial organs. Each student is presented with the case study summary along with additional text readings, website links, etc. for the following class session. Students must come to class prepared to discuss the case and, by the end of the class, formulate their own opinions about the solution to the case.

We included guest speakers based on the different case studies presented. The first session features a speaker from the philosophy department who serves as an expert on teaching bioethics principles. Our goal is that this expert will help students develop a firm foundation in solving ethical problems, which may not be achieved by case studies alone. Speakers also include faculty from the Biomedical Engineering department, Vanderbilt University Medical Center, and Vanderbilt University Hospital. Each speaker gives perspectives on the three different areas of interest for the course.

As a result of the positive outcome of the BME Goes to the Movies project, we also include three in-class films in the syllabus. *Miss Evers' Boys* is narrated from the point of view of Eunice Rivers, a nurse who worked on the Tuskegee study from 1932 to 1972. As in the BME Goes to the Movies project, we give students a pre and post-questionnaire about the ethical principles in the movie in order to evaluate the learning process of the student when viewing the film. *Cracking the Code of Life* documents the development and race to decode the human genome. Students gain a better understanding not only of the history of the project, but also on the applications and debates that have developed upon completing the project. *A Right to Die: The Dax Cowart Case* documents the life of Dax Cowart, who suffered severe burns in an automobile accident in the mid-1970s. Although Cowart begged his physicians not to treat him and let him die, they denied his wishes and gave him treatment anyway. This movie raises awareness of patient rights and allows students to hear to the points of view of Dax Cowart and the physicians who treated him.

Proceedings of the 2003 American Society for Engineering Education Annual Conference & Exposition Copyright Ó 2003, American Society for Engineering Education Page 6 of 9 The term project serves as the primary assessment tool for the course. Students are divided up into groups of four or five, and each group is given a drug research project. The goal of the research project is to recruit subjects for a non-FDA approved drug study. Students must consider methods of successful recruitment, informed consent of participants, consequences for harming participants, and compensation for participating in the study. By the end of the project, each group will turn in a written Institutional Review Board (IRB) proposal and defend the study before a panel of students and/or faculty members. Groups will be evaluated on the authenticity and clarity of the IRB proposal and the presentation of a safe and effective clinical study.

Conclusions

Our hope in creating a bioethics course for the undergraduate BME curriculum is to help students develop a clear definition of bioethics an understanding as to why a knowledge of bioethics and the ability to make informed ethical decisions is crucial in biomedical engineering today. Our primary goal is for students to learn to critically and subjectively identify and evaluate different ethical situations in bioengineering, research, and medicine and to select an appropriate course of action based on their evaluation. As a part of their undergraduate education, students should develop not only a basic understanding of engineering principles but also a fundamental sensitivity to human life and an ability to assess the importance of human life in medicine, research, and engineering applications. This course does not stand on its own, but complements the theory and principles learned during the first two years in undergraduate biomedical engineering. We hope that students will take from this course an understanding that there is no perfect solution in engineering; it is crucial for biomedical engineers to consider the risks and consequences of any design, research method, or medical treatment.

Future Plans

We feel that this project has been extremely successful, and we see huge potential with the course itself. We plan to revise and fine tune the course and present it to the departmental and School of Engineering curriculum committees to be included in the undergraduate BME curriculum. Other plans also include submitting a version of this work for publication in the *International Journal of Engineering Education*.

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BIOGRAPHICAL INFORMATION

EMILY MOWRY

Emily Mowry is a senior in the Vanderbilt University School of Engineering (VUSE). She has completed several internships in both the VUSE and the Vanderbilt University Medical Center (VUMC), including research in molecular biology, microbiology/immunology, and intracellular engineering. In addition to her contributions on this research, she plans to work with VaNTH-ERC on improving instruction in the undergraduate BME curriculum.

JERRY COLLINS

Jerry Collins is a member of the biomedical engineering faculty at Vanderbilt University, Nashville, TN. He is industrial liaison for the NSF-sponsored VaNTH Engineering Research Center in bioengineering educational technologies. Dr. Collinsís research interests have included microvascular transport and autonomic control. In addition to his membership in ASEE, he is a member of the College of Fellows of the American Institute of Medical and Biological Engineering, a member of the American Physiological Society and the American Association for the Advancement of Science, and is a board member of the Tennessee Biotechnology Association and the Tennessee Biomedical Engineering Consortium. He is a senior member of the Biomedical Engineering Society and has served the BMES as a member of the Board of Directors, as chair and member of the Interface with Industry Committee, and as editor of the BMES <u>Bulletin</u> from 1991-2001.

SEAN P. BROPHY

Sean P. Brophy received his B.S. degree in Mechanical Engineering from the University of Michigan, an MS in Computer Science from DePaul University, and a PhD in Education and Human Development from Vanderbilt University. Dr. Brophy works with the Learning Technology Center at Vanderbilt to apply current theories of Learning Science to improve instruction at various educational levels. He currently is an Assistant Research Professor in the Department of Biomedical Engineering at Vanderbilt. His current research interests relate to using simulations and models to facilitate students understanding of difficult concepts within engineering as part of the VaNTH Engineering Research Center (ERC).