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A study of biomedical engineering student critical reflection and ethical discussion around contemporary medical devices

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Abstract
Due to the impact of biomedical technologies on human wellbeing, biomedical engineering presents discipline-specific ethical issues that can have global, economic, environmental, and societal consequences. Because ethics instruction is a component of accredited undergraduate engineering programs in the US, we developed an ethics assignment that provided biomedical engineering students with a framework for ethical decision-making and challenged them to critically reflect on ethical issues related to contemporary medical devices. Thematic analysis performed on student reflections (n = 73) addressed two research questions: (i) *what* considerations do biomedical engineering undergraduates describe when asked to critically reflect on ethical issues related to contemporary medical devices; and (ii) *how* do students describe their participation in bioethical discussions? Students described design, economic factors, and empathy most frequently as considerations. Further, students reported confidence in their ability to engage in ethical discussion upon assignment completion. Overall, our analysis builds understanding of student attitudes and engagement to help inform future ethics curriculum development.

Keywords Biomedical engineering · Medical device · Ethics · Ethics education · Considerations

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Introduction

Ethics broadly defines how we discern a moral life and appraise such interpretations (Beauchamp and Childress 2009) and may differ according to one's values or beliefs. Ethics therefore gives rise to subdivisions pertaining to specific disciplines. Biomedical ethics underscores beneficence, nonmaleficence, justice, respect for autonomy, and professional-patient relationships regarding medicine, medical practice, and other human-centric treatments (Lawrence 2007; Beauchamp and Childress 2009). Emerging first from the Hippocratic Oath (Edelstein and Hippocrates 1943), Beauchamp and Childress (2009) secularized these principles that today pervade a broad spectrum of medical disciplines, from nursing to psychiatry. In the engineering discipline, codes of ethics between institutions broadly encompass these ideals in varying forms. The Institute of Electrical and Electronics Engineers (IEEE) for example, has their own set of guiding principles that place greater emphasis on business conduct and organizational standards (Fleddermann 1999; IEEE Code of Ethics 2022). Biomedical Engineering (BME) sits at the cross-roads of medicine and engineering and follows an ethics code of conduct outlined by the Biomedical Engineering Society (BMES) which blends the ethical worlds of engineering and medicine, accounting for organizational *and* human autonomy (BMES Code of Ethics 2021). With BME's far-reaching impact on society broaching subjects like facial analysis software, remote health monitors, and artificial intelligence (Fleddermann 1999; Dzobo 2020), it is also worth noting that engineering accrediting entities, such as ABET, require that ethical and professional responsibility be incorporated into student learning outcomes (ABET 2021).

For programs seeking accreditation, ABET (2021) states that an undergraduate BME curriculum must develop the student's "ability to 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," (ABET, Criterion 3, no. 4). This mandate is broad, briefly stated, and therefore subject to interpretation, allowing for implementation style to differ across programs. Classroom approaches have included case-based learning (Martin et al. 2005), stand-alone ethics courses (Peacock et al. 2013; Loui 2005), integration of ethics into engineering courses (Rayne et al. 2006), and practice-oriented ethical instruction (Bezuidenhout et al. 2020; Wittig 2013). In fact, one course valued evocation of emotion for ethical discussion (Sunderland 2014), further demonstrating the variety of methods programs are using to instill ethics curricula. ABET (2021) does articulate faculty expectations, such as a commitment to curricular development and overall competency, which reassures sensible instruction (ABET, Criterion 6, paras 1–2).

Aspiring biomedical engineers must be exposed to considerations toward ethical decisions that they may encounter during their careers, in order to prepare them for the workforce. As educators, we aim to equip student minds with an ethical vocabulary as they uncover their own moral values and provide them with such a method for ethical inquiry so they may appropriately respond when ethical situations arise. As educators, we also strive to understand how students approach unfamiliar and challenging situations to provide insight necessary to establish lasting connections with course material. This approach promotes an environment of holistic growth that benefits institutional culture as well as the student experience. By engaging students in classroom discussions about ethics, we aim to better equip biomedical engineers with the situational and adaptive expertise necessary to make ethically conscious decisions as they transition to the professional world in modern society.

Models for ethical instruction in the engineering classroom span a broad spectrum. Martin (2005) used hypothetical case studies to encourage students to develop an adaptive approach to solving ethical dilemmas (p. 9). Students were provided with an educational framework ("How People Learn" or HPL) that enables knowledge flexibility by merging knowledge, assessment, and community in an engaging, student-centered environment (p. 9–10). Compared to traditional, lecture-based instruction on ethical dilemmas, students in their study group demonstrated greater ability to think critically and display adaptive techniques when presented with novel situations (Martin et al. 2005). In another study, Peacock et al. *provided* test groups with alternative outcomes to ethical dilemmas and asked students to consider their ethical implications (2013). A "cognitive overload" effect was seen by their student population, leading Peacock et al. to conclude that ethical instruction should be, "clear, eloquent, with only a few important and salient features," (2013, p. 16). Their findings offer insight for instructors on how to direct constructive ethical inquiry for engineering students.

How and where ethics is structured into student programs is another factor to consider when designing curriculum. There exist stand-alone engineering courses devoted entirely to ethical engineering practices (Bairaktarova and Evangelou 2011; Loui 2005; Hess et al. 2017). Bezuidenhout's (2020) Schools for Research Data Science (SRDS) residential course introduces beginner students to data science basics while simultaneously covering a wide range of ethical subjects. SRDS's practice-oriented understanding of data ethics (p. 3) combines technical skill enhancement with ethical reasoning through course work rich with professional context and perspective-taking (Bezuidenhout 2020). Other engineering programs take the integration approach and incorporate ethics across pre-existing curriculum. Some researchers purport embedded ethical instruction leads to a quicker recognition of ethical dilemmas (Davis 2006). Demonstrating contextual factors and their impacts on engineering decisions ideally enables engineering students to accurately identify and understand ethical issues through an empathic lens (Davis 2006; Davis and Riley 2008; Hess et al. 2017). However, minimal empirical evidence of student ethics learning or student ability toward ethical decision-making has been presented to suggest one mode of delivery is superior to the other (i.e., stand-alone ethics course vs. modules or cross-curriculum integration). Consequently, educators would benefit from additional studies that provide empirical evidence to support specific pedagogies or approaches to ethics instruction for engineering students (Davis 2006; Hess and Fore 2018). The quality of tools provided for students can be where real growth opportunities reside. In our work, critical reflection was chosen as such a tool to engage students in ethics learning.

For this study, our working definition of "reflection" comes from Roger's (2001) systemic, concept analysis. He defines the reflective process as a way to "integrate the understanding gained into one's experience in order to better enable choices or action in the future as well as enhance one's overall effectiveness," (p. 41). Critical reflection can allow one to envision hypotheticals from new perspectives, draw on personal experience, connect their knowledge to empathetic considerations, and evaluate possible alternatives. That is not to say this is unattainable through other modes of guided instruction. Rather, this practice challenges a student's beliefs, brings awareness to their own morals, allows them to connect personal experience to course content, and deepen their learning (Ash and Clayton 2004). The capacity of critical reflection pedagogies to encourage students to connect prior learning and experiences to hypothetical professional scenarios make them well-suited to engage engineering students with ethics.

There is no shortage of proposed pedagogies that employ critical reflection as a contextualizing tool for ethical inquiry. What is lacking are publications that present rigorous analysis of qualitative student data (e.g., empirical analysis of quantized data from thematic analysis) to support their claims. For example, Bezuidenhout's ethics pedagogy proposal (2020), though exhaustive and articulate, concludes with a handful of student quotes to demonstrate the educational benefit of their reflective activities (p. 15). "Exemplar" studies (pp. 18–19) are unique and (most importantly) have robustly validated their results (Hess and Fore 2018, pp. 18–19).

Finding new ways to show students how to apply introspective reflection while steadfastly incorporating the technical skills of an engineer can be difficult, and not all institutions have the resources available to design service-learning projects as others have implemented (Wittig 2013). Most institutions are tasked with creating meaningful and lasting connections for aspiring engineers in a traditional classroom setting. Taking a psychological approach to role identity and acquisition, Loui's students wrote two one-paged reflections weekly and considered ethical issues centered around individuals and organizations (Loui 2005, p. 2). Loui's research demonstrated that an engineering course that heavily utilizes reflection left students feeling more confident in their ability to identify and reason through moral problems (Loui 2005, p. 6).

Competing pedagogies, deficient empirical evidence, and the continual expansion of contemporary medical devices combines into an opportunity for educational enhancement. Instructors must aim to equip aspiring biomedical engineers with the tools necessary to carry out biomedical engineering solutions with an ethical sensibility. For these reasons, we offer the following study of biomedical engineering student application of critical reflection and their ethical discussions surrounding contemporary medical devices.

Purpose

Our institution's BME undergraduate program began incorporating ethical inquiry and critical reflection through a backward instructional design mapped to student learning objectives (LOs). These articulated LOs target what skills the student must demonstrate, represent, or produce upon completion of study (Maki 2011). Having articulated course objectives has been proven to enhance the quality of ethics education (Hess and Fore 2018; Hess et al. 2017). Our program's undergraduate ethics curriculum LOs aim to equip students with a recognition of their professional responsibilities (Table 1). Students are taught to incorporate ethical practices when developing, refining, and communicating solutions for contemporary, ethical dilemmas. LOs are dispersed across several required courses, encouraging students to recognize and identify their own values and morals. Ethics modules are built into undergraduate course curriculum to supplement class topics. Ideally, this means nearly every semester our students experience ethical inquiry and critical reflection in at least one of their courses. The BME department is committed to improving undergraduate student ethical development through outlined learning objectives. Understanding *how* the student makes sense of nuanced subject matter and *what* considerations they prioritize can give insight to faculty reforming ethical development for STEM education.

The ethics module LOs for the course under study, taken from Table 1, were:

LO2 Demonstrate ability to engage in discussion.
LO5 Reflect on contemporary ethical issues in engineering design for biological and medical applications.

In light of these outcomes, we organized our study around two research questions:

RQ(i) What considerations do biomedical engineering undergraduates describe when asked to critically reflect on ethical issues related to contemporary medical devices?
RQ(ii) How do biomedical engineering undergraduates describe their participation in ethical discussion around biomedical topics?

Table 1 Ethics learning objectives in the bachelor's of science in biomedical engineering curriculum

Learning Objective	Desired Outcome
LO1	Recognize own values and morals
[a] LO2	Demonstrate ability to engage in discussion
LO3	[b] Demonstrate an awareness of ethical and professional responsibilities in global, economic, environmental, and societal contexts
LO4	Describe, apply, and document ethical inquiry
[a] LO5	Reflect on contemporary ethical issues in engineering design for biological and medical applications

Undergraduate biomedical engineering students are expected to meet all five learning objectives upon completion of their program (Miller et al. 2020)

[a]Learning Objectives for the course described in this study. [b] ABET (2021, October 3). *Criteria for Accrediting Engineering Programs, 2022 – 2023* | https://www.abet.org/accreditation/accreditation-criteria/criteria-for-accrediting-engineering-programs-2022-2023/

Methodology

The methods we developed for our study aim to identify and analyze what language, concepts, and methods of reasoning our students use when weighing ethical decisions. Alongside our research questions, we assessed progression of student skills as outlined by our courses learning objectives. Our thematic analysis sought to uncover relevant themes in response to RQ(i) through qualitative evidence. Students critically reflected on medical devices and biomedical ethics. We coded these reflections to identify what considerations students prioritized. The following sections provide context to our broader curricular effort, the class from which data samples were collected, and the demographic of the student participants. Furthermore, we outline the framework for critical reflection and ethical inquiry we employed in student assignments.

Participant demographics

Participants included third-year BME undergraduates from a mid-sized, urban university in the US, who were enrolled in an implantable materials course in either the fall 2020 or fall 2021 semester. We analyzed data from 73 anonymized students for this study. Students were given the option to voluntarily consent to their critical reflection responses to be used for research. Among students who opted to participate, 35 responses were provided by male students and 38 responses were provided by female students. Table 2 summarizes the participant demographics.

Course and student deliverables

Implantable Materials and Biological Response is a fall semester course that focuses on materials science, biomedical applications of materials, and the human body's response to implantable materials. The course includes an ethics module that challenges students to consider ethical dilemmas related to contemporary medical devices. Students may think of medical devices only in the context of their primary use (e.g., as implanted in the body); however, an entire life cycle is associated with any product that engineers should consider. Consequently, the developed ethics module asks students to consider and discuss the global, economic, environmental, and societal consequences of contemporary medical devices throughout their entire life cycles.

The ethics module encompassed a three-part assignment. First, each group of 3–4 students selected a medical device from a list provided by the instructor. The choices included: bioprosthetic heart valve, cardiac pacemaker, cochlear implant, contact lens, cosmetic implant, drug-eluting stent, gastric band, glucose meter and test strips, hip implant, intrauterine device (IUD), neural implant, and tissue-engineered skin. Each

Table 2 BME undergraduate student participant gender demographics (2020–2021)

Gender	
Male	49% (n = 35)
Female	51% (n = 38)

student group (n = 12 each year, one per medical device) researched what materials are used for the product and how the product is developed, tested, used, monitored, and discarded (i.e., its life cycle). Second, students participated in two class sessions that included minimal didactic instruction and ample time for discussion. These sessions provided students with an ethical vocabulary and a framework for ethical decision making before engaging them directly in discussions about ethics. Small-group (breakout) discussions were organized around ethical topics identified by groups during the first part of the assignment, and these groups noted areas of consensus and disagreement between students. Then, full-class discussions were moderated by the instructors to engage all students with shared sentiments and conflicts that were identified during the breakout sessions. Finally, each student submitted a 1–2 page reflective response describing their experience with the ethics module, the considerations they applied when making ethical decisions, and their depiction of the professional responsibilities biomedical engineers uphold. Students were provided with a framework for decision-making (Fig. 1; left) and asked to submit a critical reflection assignment that was structured using the DEAL Model (Fig. 1; right) for critical reflection.

Framework for ethical decision making

The Markkula Center Ethical Decision-Making Framework intends to serve as a guide for ethical inquiry and discussion (Markkula Center for Applied Ethics 2021). Markkula's framework, "is a tool designed to 1) help users see and identify a broader

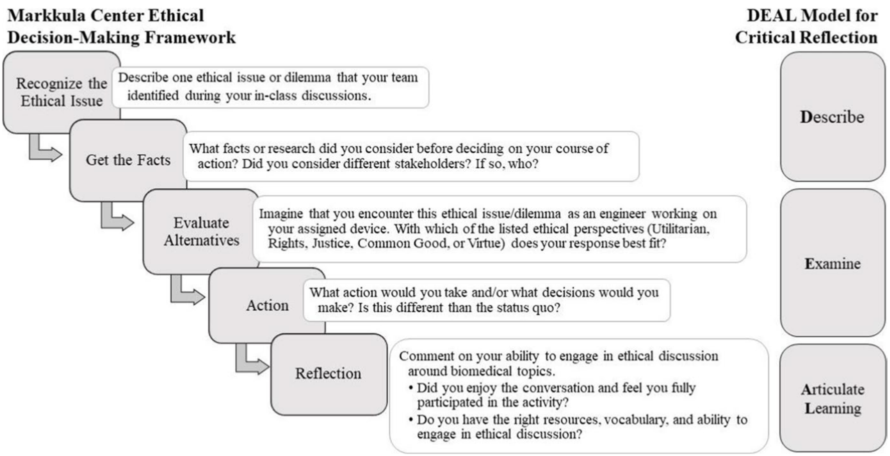


Fig. 1 [a] *Merged Markkula and* [b] *DEAL Model Critical Reflection Guide Note.* Students responded to the above prompts (middle, white) for their reflections. All prompts were a part of the same reflection submission. Prompts were structure to align with the Markkula Framework (left, grey) used throughout the ethics module. Students were instructed for the assignment to reflect using Ash & Clayton's DEAL Model for Critical Reflection (right, grey). [a] Markkula Center for Applied Ethics (2021). *Santa Clara University*. https://www.scu.edu/ethics/ethics-resources/a-framework-for-ethical-decision-making/. [b] Ash L., S., & Clayton H, P. (2004). The Articulated Learning: An Approach to Guided Reflection and Assessment. *Innovation of Higher Education*, *9*(2), 137–154 & Ash L., S., & Clayton H., P. (2009). Generating, Deepening, and Documenting Learning: The Power of Critical Reflection in Applied Learning. *Journal of Applied Learning in Higher Education*, *1*

set of ethical issues than they would have without it, and 2) guide users through a process that includes both pre-decision and post-decision steps," (Markkula Center for Applied Ethics 2021). Markkula's framework offers a stepwise method for students as they address ethical issues. With it comes a handful of suggested ethical lenses for students to consider. These lenses include common ethical paradigms that pervade across the philosophical realm (Utilitarianism, Rights, Virtue, Justice, and Common Good). While ethical paradigms exist beyond Markkula's suggestions, these perspectives were decided to be points of reference in this course and encouraged students to describe, identify, or affiliate with as an aid to their ethical decision-making process. In the course under study, students were asked to submit a 1–2-page reflection responding to prompts that closely follows the Markkula Framework for Ethical Decision Making (Fig. 1). And as part of their reflection, students were asked to identify which ethical paradigm (e.g., Utilitarian, Rights, etc.) they most identified with.

DEAL model for critical reflection

The DEAL Model is a step-by-step guide for critical reflection proposed by (Ash and Clayton 2004) which encourages students to **D**escribe, **E**xamine, and **A**rticulate their **L**earning, or "DEAL" (p. 8). Implementation of the DEAL Model was selected for the assignment due to the complexity of the subject matter while also serving to avoid the pitfalls of passive reflection by guiding students through rigorous reflection (Ash and Clayton 2004). Engaging class activities like our group discussions, lectures, and collaborative team activity coupled with critical reflection can encourage the development of the student's own learning rather than a regurgitation of what their instructors teach (Ash and Clayton 2009). Eyler and Gile's (1999) research (as cited by Ash and Clayton 2004), demonstrated that "challenging reflection helped to push students to think in new ways and develop alternative explanations for experiences and observations," (p. 4). Constructive application of the DEAL Model requires specific prompts that correlate with each step of the DEAL Model (Ash and Clayton 2009, p. 42).

Data analysis

Student participation

Student achievement of LO2 and LO5 was measured according to self-reports made in their individual reflections. Students were asked to report on the following in their reflection response:

(i) Did you enjoy the conversations?
(ii) Did you feel you fully participated in the activity?
(iii) Did you have the right resources and vocabulary to engage in ethical discussions?
(iv) Did you have the right ability to engage in ethical discussions?

For questions (i-iv), researchers categorized each response with a "yes", "no", or "Not Enough Evidence" for each prompt (i-iv). For example, when a student indicated that they enjoyed and participated in the ethical discussion, their responses were categorized as "yes" for (i) and (ii). The explicit language used by the student was our guiding principle for categorizing responses. Meaning, if a student found the ethical discussions to be "interesting," this was categorized as "Not Enough Evidence". This explicit language principle did give rise to group decisions that will be discussed further in the "Limitations" section. Authors 1–4 individually categorized anonymized, numbered student reflections. Authors 1 and 2 categorized every student reflection, Author 3 categorized even numbered reflections, and Author 4 categorized odd numbered reflections. Each student reflection was analyzed and categorized by three unique authors. After two rounds of individual scoring, followed by collaborative scoring, results were finalized and are reported in our statistical comparisons.

Qualitative analysis

Thematic analysis was used to qualitatively code student reflections, employing methods described by Braun and Clarke (2006). The research team used ten considerations published by Sanders (2022) as themes for qualitative coding. Sanders et al.'s (2022) considerations draw on the work previously published by Katz (2019), which identifies "topics that engineering faculty considered important for engineering ethics education" (as cited by Sanders et al. 2022, p. 2). Because Katz's framework was not drawn from biomedical engineering, Sanders et al. developed adapted considerations accounting for the biomedical engineering student experience. Although Sanders et al. refer to these considerations as "ethical considerations," we note that some (e.g., Economic, Technological Design) are not "ethical" as such; thus, we prefer to treat them as a list of considerations that biomedical engineering students have during ethical reflection. These considerations are defined below in Table 3 and are contextualized with examples of common topics from our own data set.

Authors 1–4 individually coded anonymized, numbered student reflections. The authors used the ten considerations from Table 3 as a codebook. Authors 1 and 2 coded every student reflection, Author 3 coded even numbered reflections, and Author 4 coded odd numbered reflections. Each student reflection was analyzed and coded by three unique authors. After individually coding student reflections, authors would meet to compare, discuss, and collaboratively code. Agreement or disagreement was determined by a three-person consensus.

Agreements and disagreements were decided based upon the presence or absence of a consideration in a student reflection. For example, if Author 2 coded the first sentence of a paragraph as "Personal", but Author 4 coded an entirely different sentence as "Personal", it was agreed that personal considerations were still present within the student's reflection. An agreement meant all three authors coded the same consideration within a reflection (Agree Present) or all three authors did not code a particular consideration within a reflection (Agree Absent). A disagreement occurred when either two authors coded a particular consideration, while the third did not, or one author coded a particular consideration, while the other two authors did not.

Table 3 Biomedical engineering student considerations during ethical reflection

Consideration	[a] Definition	[c] Example Topics
Care(ing) for Humans	Engineering ethics involves considering what actions or situations promote care for humans	Patient/user vulnerability, patient/user need, patient/user dependency, precariousness, empathy, harm reduction
Economic	Engineering ethics involves considerations pertaining to money or other forms of capital	Business practice or policy, manufacturing costs (materials, labor, overhead), business transparency, production costs, economic norms/values, competition, free market, insurance coverage
Environmental	Engineering ethics involves considering engineers' impact on the environment, especially concerning reducing environmental waste	Materials, waste reduction
Framework for Ethics	Engineering ethics involves thinking about a set of ethical perspectives, heuristics, or principles that serve as a framework for guiding ethical action	[b] Which of the listed Ethical Perspectives (Utilitarian, Rights, Justice, Common Good, or Virtue) does your response best fit?
Legal	Engineering ethics involves considering the law	Black market or unregulated markets, government funding/support, power dynamics, legal, regulations
Organizational	Engineering ethics involves considering organizational culture	Employer/employee, cognitive dissonance, company loyalty, systemic norms, redundancy, organizations related to user/patient (e.g., insurance companies, government)
Personal	Engineering ethics involves personal considerations	How personal morals/ethics, values, ideals, and religious beliefs contribute to ethical decisions as an engineer
Professional Responsibility	Engineering ethics involves thinking about necessary or good practices associated with being a professional in my discipline	Duty to serve, career identity, stakeholder consideration
Societal	Engineering ethics involves considering social contexts	Community access, community impact, social/cultural norms, values and beliefs, social or socioeconomic standing, power dynamics
Technological Design	Engineering ethics involves thinking about the technologies that engineers develop, manufacture, or produce and (often) their impacts	User/patient need, design process life cycle, product life cycle, product implications, design impact (on user), device target, considering alternatives

Above are the definitions of the considerations we applied as codes when thematically analyzing student reflections. Definitions are seen in column two while column three provides the common topics seen from our research to provide complimentary context

[a] Sanders, E. A., Hess, J. L., Miller, S., & Higbee, S. (2022, October 11). Ethical Considerations in Biomedical Engineering: Qualitative Student Perspectives from a Large Mid-Western University [Ethics and Thinking presentation]. The Frontiers in Education (FIE) Conference, Uppsala, Sweden. [b] Students were asked to identify their ethical decision/reasoning with either Utilitarianism, Rights, Justice, Common Good, or Virtue. [c] The "Context" column includes the common depictions described by our student population

After each collaborative coding session, Author 1 would gather extracts of codes where disagreements occurred. All four authors would then revisit these extracts individually, decide to keep or remove their codes, and the collaborative coding process would continue. This process of individual coding, collaborative assessment, and individual coding revising occurred a total of five sessions. Our intercoder agreement is displayed in Table 4.

Limitations

One of the reflective prompts asked our students whether they "fully participated," in the ethics module. We decided to remove "fully" from our coding procedure, because students wrote they participated in the ethical discussion, but without including the word "fully." This occurred often enough that it became relevant to change from "fully participated" to just "participated." "Participation" itself was at times a source of disagreement. An active listener, who takes the time to intentionally absorb and contextualize complex scenarios or hypotheticals, may do so quietly and without speaking. Does the absence of vocal expression designate them as absent from the activity entirely? Because our learning objective clearly expects students to "demonstrate ability to engage in discussion," it was decided that engaging in discussion was defined based upon a vocal engagement.

Trademark advantages offered by qualitative approaches exist dually as points of frustration. It is at times, "too flexible" or "too subjective," and may lead to multiple interpretations of a single idea. The only student considerations with < 90% intercoder agreement were Care(ing) for Humans and Professional Responsibility

Table 4 Intercoder agreement of consideration occurrence

Code (*N* = *73*)	Agree Present	Agree Absent	Disagree	Percent Agreement
Care(ing) for Humans	49 (67%)	12 (16%)	12 (16%)	84%
Economic	47 (64%)	23 (32%)	3 (4%)	96%
Environmental	14 (19%)	56 (77%)	3 (4%)	96%
Framework for Ethics	69 (95%)	3 (4%)	1 (1%)	99%
Legal	32 (44%)	39 (53%)	2 (3%)	97%
Organizational	20 (27%)	47 (64%)	6 (8%)	92%
Personal	41 (56%)	26 (36%)	6 (8%)	92%
Professional Responsibility	35 (48%)	25 (34%)	13 (18%)	82%
Societal	37 (51%)	29 (40%)	7 (10%)	90%
Technological Design	57 (78%)	14 (19%)	2 (3%)	97%
Total	401 (55%)	274 (38%)	55 (8%)	93%

Instances where all coders did not code a consideration was marked as "Agree Absent" (column three). Conversely, when all coders agreed a consideration was present, this was marked as "Agree Present" (column 2). Percent agreement was calculated by the summed agree present and absent values to the total cases present (*N* = 73)

(Table 3). A student would stress the value of human life, clearly demonstrating a consideration for people. Whether or not this was coded as an instance of Care(ing) for Humans became a question of whether or not the student was valuing human life from the perspective of a biomedical engineer. Despite attempts to clearly delineate Care(ing) for Human's definition across repeated rounds of coding, disagreements persisted. It became apparent Care(ing) for Humans was too subjective at times. Professional Responsibility posed similar issues and was therefore addressed in the same fashion.

A question of significance arose throughout the coding process. Students were instructed to respond to specific prompts for their critical reflection submission (Appendix A). For example, students were asked, "imagine that you encounter this ethical issue/dilemma as an engineer working on your assigned device. What action would you take and/or what decisions would you make?" If students were prompted to reflect on specific considerations, it may make their presence in a reflection less significant. Thus, we concluded that the reflection must contain clear and concise descriptions or examples of a consideration to be coded as containing that consideration. Uniquely, Framework of Ethics was a consideration that was explicitly introduced to students. Specifically, the instructor introduced the Framework of Ethics description and guiding frameworks (DEAL and Framework for Ethical Decision Making), asking students to use these frameworks to weigh contemporary issues in biomedical engineering. Therefore, Framework of Ethics and its frequency of occurrence was not considered representative of our student data set. Instead, it became an opportunity to evaluate differences between genders and their paradigm affiliations.

Two-proportion Z-Test

A Two-Proportion Z-Test was performed to identify differences in the frequency of student consideration occurrence between male and female students. Our null hypothesis assumed there would be no difference between genders when students were asked to critically reflect on ethical topics in contemporary biomedical engineering. All statistical calculations were performed in Microsoft Excel and any results with $p < 0.05$ were considered significant.

Results

The following tables present our findings of learning objective attainment (Table 5), quotes that signified the presence of a consideration in a student's reflection (Table 6), and a comparison of considerations (Table 7) and paradigms between genders (Table 8). Students favorably reported on their experience with ethical discussion and inquiry (85%). The majority reported having the proper resources and vocabulary for ethical discussion and felt confident in their ability to engage (66% and 58%, respectively).

Students discussed all ten considerations, but some considerations were more prevalent than others. Biomedical engineering undergraduates prioritized Care(ing) for Humans (67%), Economic (64%), Personal (56%), Societal (51%) and Technological Design (78%) considerations most often when asked to reflect on ethical dilemmas (Table 7). The reflection assignment instructed students to designate their ethical reasoning using an ethical paradigm from a list of paradigms we provided (Appendix A). We therefore do not consider the Framework of Ethics consideration occurrence (95%) to be representative in the same way, thus, we omit it from our interpretation of statistical analysis (Table 7). Students were least likely to weigh Environmental (19%) and Organizational (27%) considerations when discussion ethical, engineering practices or decisions. Professional Responsibility (48%) and Legal (44%) considerations were also reported.

While we did not consider Framework of Ethics consideration occurrence representative of our students' relative prioritization (as it was the only consideration explicitly introduced in the course), we did explore the likelihood of ethical paradigm affiliation between genders (Table 7). Female students were more likely to approach ethical reasoning from a Common Good (34% of females reported vs. 20% of males) standpoint (Table 8). Male students were more likely to approach ethics using Virtue standards (31% males reported vs. 21% of females).

Discussion

Student's perceptions of learning outcome achievement

Biomedical engineering's rapidly evolving knowledge base continually redefines what we consider fundamental knowledge. As such, aspiring biomedical engineers can appreciate the impact their designs have on individuals, society, business, and even politics through pedagogies that foster adaptive expertise (Martin et al. 2005; Hatano and Inagaki 1986; Fleddermann 1999). Just as students learn how to approach design, students must be equally prepared to tackle ethical dilemmas. Students require an ethical vocabulary, an awareness of one's own morals, and a method of ethical inquiry to be able to process, discuss, and adjust when ethical situations arise. Results indicate the majority of students achieved the learning objectives outlined by our ethics module curriculum. Positive experiences self-reported by our students suggest a favorable experience with our ethics module. Many students not only enjoyed (85%) the ethics module but felt reassured in their ability to engage (58%) in ethical discussion (Table 5).

> "I found it helpful to try to produce ethical solutions to the best of my ability while also bearing in mind that there essentially is no correct or "better" answer." *(Student 7)*
> "I enjoy ethical discussions because each argumentative point has merit, but some points have more weight than others." *(Student 30)*

Student 7's recognition "that there essentially is no correct or 'better' answer," and *Student 30's* appreciation for "argumentative merit" suggests the ethics module fostered their appreciation for the contextual nuance biomedical engineers balance when providing contemporary medical solutions.

Table 5 LO2: demonstrate an ability to engage in ethical discussion

Did you enjoy the conversation?			[a] Do you feel that you fully participated in the activity?			Did you have the right resources and vocabulary?			Do you feel you have the ability to engage in ethical discussion?		
Yes	No	NA	[a] Yes	No	NA	Yes	No	NA	Yes	No	NA
62 (85%)	3 (4%)	8 (11%)	43 (59%)	2 (3%)	28 (38%)	48 (66%)	1 (1%)	24 (33%)	42 (58%)	1 (1%)	30 (41%)

Students were asked to include a description of their engagement in the ethics module by answering the four questions from row 1. If a student did not address the question, or did not address it explicitly (e.g., "I enjoyed these conversations and feel I participated" versus "it was nice being a part of the discussion"), their responses was recorded as "Not Enough Evidence"

[a] "Fully participated" and "participated" were counted as "Yes"

Table 6 Example quotes for undergraduate biomedical engineering student considerations

Consideration	Example Quote
Care(ing) for Humans	"This is the way that I would like to conduct myself, with **putting people first.**"
Economic	"Even if a **company** understands this problem, they will not be able to stay in **business** if they lose **money** on their **products**."
Environmental	"First, packaging can be made smaller **to reduce waste**."
Framework for Ethics	"**A Common Good viewpoint** would dictate that even beyond it being allowable so long as it helps more than it hurts, there is an obligation to produce this band and increase the overall health of society."
Legal	"I would suggest that the company performed extra testing **to avoid patient injury and legal action**…"
Organizational	"**As an employee**, your primary interest lies by default with the executives of the company who enable the research and pay your salary."
Personal	"Before choosing my course of action, **I considered my background experiences** with [d]eaf people and the information I learned during my ASL classes."
Professional Responsibility	"Thus, it is our **responsibility as a biomedical engineer** to focus on these consumer needs and meet them accordingly."
Societal	"**In an ideal world we all would care about society as a whole**, I don't think that is easy when there are so many selfish **people with power**."
Technological Design	"**Reducing the thickness** of the long-lasting contact lenses would make them **more comfortable to wear**."

Bolded text identifies the key language from a student quote that connects it with the given consideration

Table 7 Occurrence of considerations between genders

	[a] Total Occurrence *N = 73* (# Students, % of Students)	Female Students *n = 38* (# Females, % of Females)	Male Students *n = 35* (# Males, % of Males)
Care(ing) for Humans	49 (67%)	30 (79%)**	19 (54%)**
Economic	47 (64%)	28 (74%)**	19 (54%)**
Environmental	14 (19%)	9 (24%)	5 (14%)
Framework of Ethics	69 (95%)	35 (92%)	34 (97%)
Legal	32 (44%)	17 (45%)	15 (43%)
Organizational	20 (27%)	7 (18%)**	13 (37%)**
Personal	41 (56%)	22 (58%)	19 (54%)
Professional Responsibility	35 (48%)	21 (55%)**	14 (40%)**
Societal	37 (51%)	22 (58%)**	15 (43%)**
Technological Design	57 (78%)	30 (79%)	27 (77%)

[a] "Total Occurrence" was the total count where all coders agreed the code was present within the student's reflection *("Agree Present",* Table 3*, column 2)*

***$p < 0.05$, Two-Proportion Z-Test*

Table 8 Frequency of ethical paradigms between genders

	Total Occurrence [a] *N = 73* (# Students, % of Students)	Female Students *n = 38* (# Females, % of Females)	Male Students *n = 35* (# Males, % of Males)
Rights	10 (14%)	5 (13%)	5 (14%)
Virtue	19 (26%)	8 (21%)**	11 (31%)**
Justice	5 (7%)	2 (5%)	3 (9%)
Common Good	20 (27%)	13 (34%)**	7 (20%)**
Utilitarian	32 (44%)	15 (39%)	17 (49%)
Non-Identified	7 (10%)	5 (7%)	2 (3%)

[a] Some students classified their reasoning using more than one ethical paradigm. For this reason, summed percentages will exceed 100%

***$p < 0.05$, Two-Proportion Z- Test*

There was notable variety in participation and engagement styles. On occasion, a student would describe their experience with ethical discussion positively, then go on to say their participation was low.

> "I might not fully participate in the conversation, but I enjoy being a part of it…I like to hear what other people think of the ethical issues…" *(Student 56)*
> "Overall, the discussions were enjoyable, and I feel that I participated adequately, but not fully enough - getting more than I gave." *(Student 19)*
> "I did some more talking that I normally would have…I don't believe I fully participated but I did more so than normal." *(Student 13)*

Excerpts like these seen with *Student 13, 19,* and *56* occurred enough that our team had to formally agree on the definition of "participation". We asked ourselves, what does it mean to participate, what does it look or sound like, and does it always look the same? Conversation is a balance between give and take. Participation may appear in the form of attentive and intentional listening. Others learn best through visual or auditory means. Because our learning objective (LO2) encourages students to engage in ethical discussion, it was agreed that a confirmed instance of participation was a vocal or interpersonal engagement. This decision both explicitly addresses our learning objective and leaves no room for subjectivity in our empirical analysis. But engagement styles (such as active listening) could suggest our student's participation, vocabulary, and ability to engage in ethical discussion is greater than what is reported in Table 5.

Other students appeared eager to learn more from their peers:

> "The way conversations were split up allowed me to meet with people with differing views than me which pushed me out of my comfort zone to disagree with my peers." *(Student 80)*
> "It is nice to hear the perspectives of those who don't think like me as well as explore new ideas I hadn't considered before." *(Student 49)*

> "Participating gave me an idea of what everyone else was thinking about the issues that I may or may not agree with myself." (Student 12).

Students who reported high degrees of participation (such as *Student 12, 49*, or *80*) may suggest the framework, vocabulary, and resources provided for students reinforced their confidence and ability to participate in conversations surrounding ethics. Students with like this were more likely to cite their knowledge on the subject as a positive influence on their participation:

> "I enjoyed participating in the ethical conversations. I felt prepared for these conversations, as I researched the topic in depth and found multiple points of ethical discussion." *(Student 66)*

Student consideration trends

Economic, personal, societal, and technological design considerations

The prevalence of certain student considerations compared to others is a noteworthy finding. Biomedical engineering undergraduates prioritized Economic (64%), Personal (56%), Societal (51%) and Technological Design (78%) considerations most often when asked to reflect on ethical dilemmas (Table 7). These considerations also had consistently high intercoder agreement (Table 4). Recognition of ethical issues brought by biomedical engineering decisions was consistently achieved by our students. While many students were able to grasp ethical complexity from the lens of self (such as with *Student 7*'s appreciation for contextual nuance), abstract hypotheticals from a macroethics perspective fell short. Many failed to expand beyond a basic recognition of the ethical issues or did not include connections tying the considerations together. If students were able to interconnect the considerations, they did not include these evaluations in their reflections. The kind of abstract reasoning ethical inquiry requires may be challenging to the novice student. Research assessing the biomedical engineering student experience with ethical discussion demonstrated high school students and first-year college students with less exposure to the biomedical engineering field were able to incorporate adaptive decision-making processes more easily than upper-level students (Rayne et al. 2006, p. 4). This suggests development of adaptive expertise is more influential in a student's earlier years. Given our student population for this study included third-year undergraduates, simple recognition of ethical dilemmas that lacked macro-causal impact coincides with the current research (Martin et al. 2005; Rayne et al. 2006).

Technological Design was reported as one of the highest occurring considerations amongst biomedical engineering students (78%). Risk associated with improper design was consistently of the upmost concern:

> "There are still many risks that are involved with cochlear implants both surgical and non." *(Student 24)*

> "By creating a more successful iteration of the current process, the deaf community may lessen their contempt toward implant surgery because at least the risk is reduced." *(Student 39)*

Technological design considerations appeared most often in the form of device testing and implementation and their respective risks to the user or patient. An appreciation for the cost of design was also apparent. Economic considerations by students almost exclusively described costs (i.e., cost of testing, cost of testing and their effect on a company, final cost of a product, or final cost of a product and its relationship to the patient/user). It was common for students to be at odds with the fiscal constraints. *Student 8* wrote:

> "[Cutting costs for testing] makes it much easier for companies to produce new devices quicker and cheaper, but the question remains if this is a dangerous way to decrease important testing...I understand that it is important to try and make products less expensive for companies so that patients don't have to go broke to experience good health." *(Student 8)*

Societal (64%) and Economic (51%) considerations frequently occurred together. Examples from students referenced socioeconomic groups, their respective needs, and these groups' fiscal constraints. An appreciation for the distribution of power, contemporary systemic norms, and inherent commercial value emerged as a trend when students would weigh societal and economic considerations in tandem:

> "A prevalent ethical dilemma is the cost of medical devices due to the testing requirements that companies have." *(Student 41)*
> "Other considerations, such as access to the Internet have to be considered, along with the monetary aspect of an elective cosmetic surgery." *(Student 57)*
> "In an ideal world we all would care about society as a whole[.] I don't think that is easy when there are so many selfish people with power." *(Student 81)*

Legal, care(ing) for humans, and professional responsibility

Professional Responsibility (48%) and Legal (44%) considerations were moderately reported. However, Intercoder agreement (Table 3) for Professional Responsibility (as well as Care(ing) for Humans) is noticeably lower than other considerations (82% agreement with Professional Responsibility and 84% agreement with Care(ing) for Humans). Concern for patients/users and the professional responsibilities that come with being a biomedical engineer were subtly inferred and interwoven with more obvious considerations. For example:

> "A wheelchair is but one example of price [gouging] on a medical device that is essential for multiple people…. The testing is there to protect the patient, and there is a reason for such testing…" *(Student 9)*

The concern and care for patients/users is not explicit in this passage. It is implied through tone, language, and the choice to include the patient's needs ("essential for multiple people" and "protect the patient"). What is explicit are economic ("price gouging") and technological design ("testing") considerations. This example illustrates it was difficult to reach a consensus when concern for persons was implied but never directly expressed. While Care(ing) for Humans was a consideration interwoven across many contextual factors, Professional Responsibility was a consideration muddied by the personal interpretation of responsibility and duty, as well as the difference between responsibility as a biomedical engineer and the responsibility of others. As students explored their moral values, critical reflection did not always pertain specifically to the biomedical engineering profession. Gelfand's (2016) engineering ethics class worked backwards by focusing on why someone may act unethically (p.1). Students were encouraged to "take off your engineering hat and put on your management hat" as they critically reflected on what goes wrong in unethical scenarios (Gelfand 2016, p. 18). By way of moral psychology and critical reflection, students were challenged to view people or situations as neither inherently "good" nor "bad," and instead as respondents to situational factors that affect moral judgment and behavior (2016, p. 13).

Environmental and organizational

Students were least likely to weigh Environmental (19%) and Organizational (27%) considerations when making ethical decisions. Reflection prompt instructions asked students to imagine themselves in the workplace and contemplate the impact of employee/employer relations on ethical reasoning. Yet Organizational considerations were continually outcompeted. This may suggest it was easier for undergraduates to reach for more familiar topics like empathy, economics, or design than to imagine organizational impact in a professional setting they have yet to experience. Furthermore, this ethics module addressed entire life cycles of contemporary medical devices, from inception to disposal. Resource allocation and access connect with environmental considerations, either directly or indirectly. Medical device production and disposal were commonly considered when their assigned device had more obvious implications (e.g., disposable contact lenses). Students in small groups researched the production and eventual disposal of a single biomedical device from a provided list of options (including gastric bands, contact lenses, or cochlear implants) before exploring their ethical implications (Appendix A). Disagreements around the use of cochlear implants and gastric bands in non-adult patients, for instance, can quickly drive discussion toward social topics such as rights or consent, leaving less room for topics geared towards environmental impact. This could be why Organizational and Environmental considerations were the least prioritized by undergraduate students despite the focus that the ethics module placed on product life cycle.

Gender disparity in biomedical engineering student considerations

Although Organizational considerations were least mentioned overall, male students were almost twice as likely to account for organizational factors impacting their overall ethical reasoning. Conversely, our female students placed greater emphasis on empathic (Care(ing) for Humans) and fiscal (Economic) factors influencing their ethical reasoning (Table 7). Rather than an assessment of learning objectives, Table 7's comparison may instead suggest a stronger connection to modern gender trends or norms seen within engineering professions. Gender comparison was assessed for consideration occurrence (Table 6). Biomedical engineering as a profession displays a stark gender parity when compared to most other engineering divisions. Forty-one percent of biomedical engineering degrees in 2017 were awarded to women while less than 15% of electrical and computer engineers identified as female (Chesler et al. 2010; Potvin et al. 2018; Yoder 2017). With women pursuing engineering majors at a completion rate comparable to men (Lord et al. 2009; Ohland et al. 2008; Potvin et al. 2018), research suggests the engineering divide could be attributed to social and cultural beliefs held by students *before* they begin their college careers (Potvin et al. 2018). This draw to helping others we identified coincides with Potvin's (2018) analysis of female engineer interests favoring bioengineering/biomedical engineering major (pp. 4–5). Potvin's study emphasized that, when compared to other engineering professions, bioengineering/biomedical engineering majors across the board display greater interest in communal/relational expectation, particularly amongst women (2018, p. 6).

We identified differences in ethical lenses between genders inductively over the course of our analysis. We began exploring the likelihood of males and females to affiliate with a certain ethical paradigm (Table 8), with some students classifying their reasoning using more than one ethical paradigm (thus summed percentages exceed 100%). Female students were more likely to approach ethical reasoning from a Common Good (34%) standpoint. Male students were more likely to approach ethics using Virtue standards (31%). Often, students would classify their reasoning with a particular ethical paradigm, only to support their argument with vague or incorrect definitions and applications (e.g., a student defining their decisions from a Rights perspective on the grounds their decision would benefit most people; a standard upheld by Common Good philosophers). Students had difficulty understanding the subtle nuance between approaches or how their respective drives lead to distinct solutions. *Student 24* wrote:

> "I believe [I] sit in having a utilitarian view because I would want the patient to get the best care and be able to be happy with their decision." *(Student 24)*

Students, like *Student 24,* in favor of Utilitarianism were quick to support their decision with the "does more harm than good," adage. Ethical solutions may approach conflict from distinct planes, but all strive to attain some form of respect, dignity, satisfaction, or harm reduction. Approaches differ in their drives, standards, and definitions of what constitutes moral behavior (Markkula 2021). Overall, students were more inclined to affiliate their moral reasoning with Utilitarianism (49% overall, 39% Female, and 49% Male). It may be reasonable to assume most people seek to do more good than harm as the Utilitarian adage highlights. We cannot say definitively students failed to grasp the subtle nuance between ethical lenses. Students swayed between being entirely wrong or vague, to demonstrating early abstract-reasoning skill development. Subtle nuances between paradigms were not lost on all students. Several walked away from the module with a greater appreciation for the contextual distinctions ethical dilemmas propose:

> "I really enjoyed the ethics discussions we had in class...I noticed some problems could be very different, but the ethical concern could be the same. [F]or example the issue of disposing contact lenses and glucose strips or the safety concerns related to genetically modified products, organs etc. [It] provid[ed] me with a lot to think about over the course of time." *(Student 45)*

Lim's (2021) study revealed a stark difference between undergraduate engineering students' comprehension of microethics (engineering ethics from the individual perspective) and macroethics (collective social responsibility from a large-scale institutional standpoint). Students struggled to connect their individual perspective to great social contexts. Many defined social relevance of engineering implications based on pragmatic and immediate usability of technology (pp. 17–19), either missing the greater social implications completely or "intentionally ignored" (Lim et al. 2021, p. 15). Disconnect between immediate and greater contexts for Lim's study manifested in critical reflections in the form of apathy (2021, p. 15). Their results indicated engineering students favored technical course content over abstract, ethical inquiry. Our results did not depict an apathetic regard for ethical discussion and the majority reported favorably their experience and eventual achievement of LO2. Students would even envision a future, idyllic self, one who was more well-read and familiar with contemporary medical device ethics.

Limitations

While we believe that our study is a mostly thorough analysis of biomedical engineering student behaviors and attitudes during ethical reflection, there are some limitations to our methodology that in some cases prevent us from drawing sharper conclusions. First and foremost, our study relies almost exclusively on data that students "self-report" through their reflection writing. We did not perform any additional tests to attempt to confirm or validate the responses that students gave. Nonetheless, we have no reason to believe that students were dishonest in their reflections, so we feel that our study accurately depicts their considerations during ethical reflection. Our analysis of student ability to engage in ethical discussion (Table 5) did rely on direct self-assessment from students, so our study is able to demonstrate only that students *feel* prepared to engage in ethical discussion. A more rigorous approach would be required to fully assess student *ability* to engage in ethical discussion.

Another significant limitation of our study involves variability in the topics on which students reflected, which was a result of the design of the assignment. Student teams were encouraged to select different medical devices to explore at the onset of the assignment. Further, in choosing topics for their ethical reflections, students were allowed to select any ethical issue that came up during the in-class discussions. Consequently, students reflected on ethical issues related to a broad range of medical devices, which may impact their considerations during ethical reflection. For instance, would a student reflecting on the ethical issues related to a cochlear implant describe the same considerations if they were instead discussing a hip replacement? This is a type of question that we considered studying, but we did not have enough data to reliably assess whether a student's choice of medical device impacted the considerations coded in their reflections. In the end, we felt that since students reflected on ethical issues related to a broad range of medical devices, any bias introduced into our data by this variable should be minimal.

Conclusion

The data generated indicates this course achieved the LOs set out for the ethics module (Table 5). Providing students with a framework and the vocabulary necessary to participate in ethical discussion led to greater student participation, enjoyment and ability to engage in ethical discussion. Our work suggests consideration prioritized by biomedical engineering students were gender specific. When asked to critically reflect on contemporary medical device life cycles and overall impact, males placed greater emphasis on organizational factors while females were more likely to describe empathetic and economic considerations. Male students were more likely to approach ethical dilemmas from the perspective of virtue while female students based their decisions off supporting the common good of all persons. Regardless of gender, environmental considerations were described the least by biomedical engineering students. Care for humans, economic constraints, consideration for technological design, and personal conjecture appeared most often within biomedical engineering student reflections.

Introducing engineering students to topics addressing ethical responsibility may sensitize them to prevalent issues before facing them in a professional environment. Students as a result maybe be more apt to think critically and independently to resolve issues in an ethical manner (Fleddermann 1999). Many models promote self-reflection as the first step towards applying ethical inquiry. Students overall reported greater confidence in their ability to engage in ethical discussion. Instructors must provide the tools necessary for critical reflection in ethical inquiry as students navigate and define their values and expand further their understanding of social implications brought about by modern biomedical devices. Tools such as vocabulary, problem-solving, and abstract reasoning could be attained successfully by constructive critical reflection. Additional empirical evidence can contribute to support this claim.

Appendix A

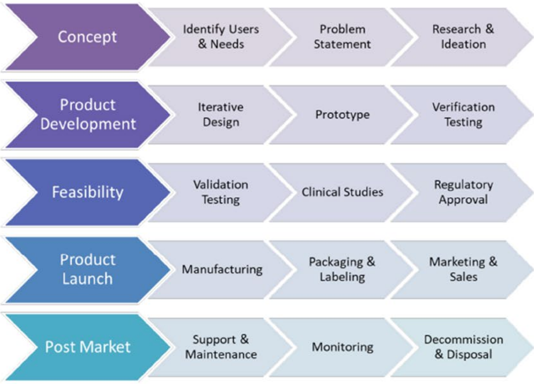
Ethics Module Assignment

BME 38100: Implantable Materials & Biological Response, Fall 2021

BME Program-Level Student Learning Outcome (LO2): Students will demonstrate ability to engage in discussion.
BME 38100 Student Learning Objective/Outcome: Students will critically reflect on the life cycles of contemporary medical devices, identifying potential ethical issues related to device manufacture, use, sale, and disposal.

COURSE ASSIGNMENT: Ethical Awareness & Discussion – Medical Device Life Cycle

Background: In your sophomore BME courses, you were introduced to ethical inquiry and the notion of ethical awareness. These concepts were introduced in assignments related to the use of animals in biomedical research and noninvasive measurement of human signals. In this course, which focuses on materials used by biomedical engineers, we will discuss ethical issues surrounding medical devices. We often think of medical devices only in the context of their primary use (e.g., as implanted in the body); however, there is an entire *life cycle* associated with any product that we as engineers must consider. This process begins with a concept or idea and ends with the disposal of a device (see the figure below for one framing of the device life cycle). The decisions that we make as biomedical engineers can have global, economic, environmental, and societal consequences. This assignment will ask you to consider and discuss the ethical issues associated with medical devices, throughout entire life cycles.



Before continuing with this assignment, please review the attached document, *Ethics for BME Students*, to review relevant terminology, concepts, and our shared framework for ethical decision making.

What to Do:

Step 1
In your assigned teams: 1) select a medical device from a provided list of options, 2) do research to identify the materials used in the manufacture and use of the device, and 3) summarize the total life cycle of the device.

Summarize your research in an organized outline. Submit on Canvas by Sunday, December 5th (11:59 pm).

Step 2
Attend and participate in two class sessions focused on ethical issues associated with medical devices:

> **Session 1: Ethical Issues Associated with the Device Life Cycle:** What possible ethical issues might be associated with the manufacture, sale/marketing, use, and disposal of your selected device?
>
> **Session 2: Considering Ethical Issues from Different Perspectives:** How do different ethical actors come to decisions or actions when considering ethical situations?

Use the outline at the bottom of pg. 2 of this assignment to organize your thoughts prior to attending the sessions.

Take notes on your assigned Google Slides on Monday, December 6th and Wednesday, December 8th.

Step 3

After doing research with your team and participating in small- and large-group discussion, your final assignment is to reflect on the experience and to look forward. Address the prompts below in a 1-2 page written response:

- Describe one ethical issue or dilemma that your team identified during your in-class discussions.
- Imagine that you encounter this ethical issue/dilemma as an engineer working on your assigned device. What action would you take and/or what decisions would you make? Is this different than the status quo?
- Referencing the *Ethics for BME Students* handout, reflect on your response to the previous prompt:
    - What facts or research did you consider before deciding on your course of action?
    - Did you consider different stakeholders? If so, who?
    - With which of the listed Ethical Perspectives (Utilitarian, Rights, Justice, Common Good, or Virtue) does your response best fit?
- Choose one of the remaining Ethical Perspectives and consider how someone with that perspective may act differently or make different decisions than you.
- Finally, comment on your interest and ability to engage in ethical discussion around biomedical topics.
    - Did you enjoy the conversations and feel that you fully participated in the activity?
    - Do you have the right resources, vocabulary, and abilities to engage in ethical discussions?
    - *Optional:* Did you and any of your teammates arrive at any disagreements or exhibit different ethical perspectives? Elaborate.

Submit this individual reflection essay on Canvas by Sunday, December 12th (11:59 pm).

Reflection: Please consider the questions below, which are organized according to our shared framework for ethical decision making, to help guide your discussion and reflection:

Recognize the Ethical Issue: Identify ethical issues around your chosen device, being sure to consider its entire life cycle. Specifically, what choices or decisions are engineers making that may have ethical ramifications?

Get the Facts: What additional information do you need to gather to fully understand the issue? Who are the stakeholders and societal groups affected? What options do the stakeholders/groups have for actions/decisions?

Evaluate Alternatives: In considering the options identified in *Get the Facts*, evaluate these alternative actions by answering one or more of the following questions.

- Which would produce the most good and do the least harm?
- Which option best respects the rights of all who have a stake?
- Which option would treat people equally?
- Which option best serves the whole community?
- Which option leads you to be the sort of medical device employee you'd want to be?

Action and Reflection: Provide your own analysis of how the engineers and companies that produce your chosen device should act. Specifically, discuss how your own awareness of ethical and professional responsibilities helped you develop your reflection.

Appendix B

Ethics for BME Undergraduate Students

What is Ethics?

"Ethics is a field of study that examines the moral basis of human behavior and attempts to determine the best course of action in the face of conflicting choices. Ethics is central to our human experience and provides an organizing dimension to human interaction. Because it invokes questions that consider morals, values, and principles, and because it seeks to consider and respect alternate viewpoints, it is a key component to living within a society in a civilized way."

(NWABR, *An Ethics Primer*, 2009)

"Ethics is a concern with the basic needs and legitimate expectations of others as well as our own."

(Weston, *A 21st Century Ethical Toolbox*, 2008)

What are Values?

"Values are [the] things we care about, that matter to us; those goals and ideals we aspire to and measure ourselves or others or our society by." (Weston)

Examples: Caring, Charity, Community, Compassion, Dedication, Diversity, Empathy, Equality, Fairness, Generosity, Hardworking, Honesty, Humility, Justice, Loyalty, Patience, Relief of Pain and Suffering, Respect for Persons, Reliability, Respect, Responsibility, Self-Discipline, Tolerance, Well-being

How are Morals and Ethics Different?

"When we speak of 'morality' we are more likely to think of the values involved as fixed, not in question. A 'moral' person almost reflexively does what's right, while an 'ethical' person is likely to be less sure, or more concerned about issues where values are more in flux or at odds." (Weston)

A Framework for Ethical Decision Making

Recognize the Ethical Issue → Get the Facts → Evaluate Alternatives → Action → Reflection

1) **Recognize the Ethical Issue:** Could this situation be damaging to someone or some group?
2) **Get the Facts:** Summarize the situation.
   a. What are the relevant facts?
   b. Can I learn more about the situation to make a more informed decision?
   c. What individuals or groups are relevant actors and/or stakeholders?
3) **Evaluate Alternatives:** Evaluate options by applying relevant ethical perspectives.

Ethical Perspectives	
Utilitarian	Which option will produce the most good / least harm?
Rights	Which option best respects the rights of all stakeholders?
Justice	Which option treats people equally?
Common Good	Which option best serves the whole community?
Virtue	Which option leads me to act as the person I want to be?

4) **Action:** Implement decision with care and attention to concerns of all stakeholders.
5) **Reflection:** How did the decision turn out and what have I learned from this situation?

(Markkula Center for Applied Ethics, 2009)

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Data availability Due to the nature of this study, supporting data is not available. The participants did not give consent for their data to be shared publicly.

Declarations

Ethical approval All methods described in the manuscript that will involve human participants have been granted exemption by the [redacted] Institutional Review Board (IRB) under protocol number 2007679809.

This work was approved by the Indiana University IRB: #2007679809.

Consent to participate Students consented to participate in this study per the Indiana University IRB: #2007679809.

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