Ethics of Regulated Biomedical Device Design

Prof. Nael Barakat, Grand Valley State University

Dr. Nael Barakat is a professor of Engineering at Grand Valley State University (GVSU), Grand Rapids, MI. He is a registered professional engineer in Ontario, Canada, and a fellow of the American Society of Mechanical Engineers (ASME). Dr. Barakat holds a Ph.D. in Mechanical Engineering from McMaster University, Canada. His areas of interest include Controls, Robotics, Automation, Systems dynamics and Integration, as well as Engineering Ethics, professionalism, and Education. Dr. Barakat is serving as the chair of the Technology and Society (T & S) Division and as the ASME district B leader. He also serves as the treasurer and secretary for the ASEE Engineering Ethics Dvision.

Ms. Nadia Sunny, Grand Valley State University

Nadia Sunny is pursuing a Master's degree in Biomedical Engineering at Grand Valley State University, Michigan. She received her Bachelor's in Chemical Engineering from Bangladesh University of Engineering and Technology in 2004 and Master's in Business Administration from Institute of Business Administration, Dhaka University in 2008. She has a diverse work experience in mechanical fabrication company, urea process plant, telecommunication equipment vendor and bank. She received excellence awards from her employer in 2009, 2011 and 2012 for successful project management. Her areas of work and research interest are device design and regulation on medical devices.

Mr. Md Mehedi Hasan, Grand Valley State University

I have been working as a research assistant in supply-demand planning of Lithium-ion batteries for electric drive vehicles while pursuing my MS in Product Design & Manufacturing Engineering in Grand Valley State University. I pursued my bachelor in Industrial & Production Engineering from Bangladesh University of Engineering & Technology in 2012. My areas of interests are manufacturing processes, quality management, supply chain management etc.

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Safety and welfare of human beings is the top priority of all codes of ethics for engineers. At the same time, market wants more useful and effective products from engineers in no time. Engineers working directly with the health sector, i.e. biomedical engineers, often have to struggle in making design choices to balance these demands for the very sensitive nature of the sector. Regulation and monitoring for this field of engineering is more heightened than any other for the same reason. This adds to the biomedical device design engineer's list to comply with, or risk to be alleged for.

Literature shows that biomedical engineers usually go through a number of dilemmas in different stages of a device design. Examples of these dilemmas include: sufficient safety of the user, need for clinical trials, and confidentiality level of the patient's data. These are examples of the issues reported as unresolved in most cases. While the regulator, the Food and Drug Administration (FDA), wants the device and its development process to be full-proof, and the code of ethics wants these to be ethical, the design engineer is left to make a balanced and correct choice. The fact that these issues end up being unresolved reveals a multifold opportunity for improvement. First, the existing code of ethics for biomedical engineers, from the Biomedical Engineering Society (BMES), is not currently adequate, with its broad nature, to help the engineer find a balanced decision and yet design a device that is safe and effective. Second, the education of biomedical engineers, particularly in the area of ethics, seems to be insufficient to equip them with what they need to overcome these hurdles. Third, the regulatory process in spirit agrees with the code but includes its own challenges.

This calls for an in-depth study of the ethical issues encountered in biomedical device design as well as additional clarification of the code of ethics, which influences both the student and the practicing engineer. It also calls for a check on the curriculum content related to the area of ethics and regulations, within biomedical engineering education programs. Screening through twenty leading universities shows evidence of ethics studies in engineering within different courses. However, presence of a thorough study on biomedical engineering ethics, for instance – a dedicated ethics course, is found in only one of them. Based on these findings, it is recommended that a weighty inclusion of studies on ethics, integrated with regulation, be part of the curriculum of biomedical engineering education. Recommendations to improve the existing code of ethics in this field are proposed as well as a discussion of integrating the code and the FDA regulation in the curriculum for biomedical engineers, to improve the situation.

Keywords: Biomedical engineering, engineering ethics, biomedical device design, medical device regulation, device licensing.

Introduction

Biomedical engineers work directly with the health sector. This is a very sensitive area for its very nature and close involvement with human life. As a result, ethical concerns of the biomedical device design engineers as well as regulation on medical device development and marketing are both high. While market always wants more useful and effective devices from the engineers, concerns on ethical issues are reported that the device design engineers struggle to resolve[1]. This is in addition to the risk of failing to comply with the regulation, which adds up another dimension to their dilemma.

The term biomedical device means, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes[2]. This definition by United States FDA reflects how closely the biomedical devices interact with human life and functionality.

When faced by ethical concerns in different stages of designing such devices, engineer's first resource to look for guidance, based on their education, would be the code of ethics[3]. Code of ethics, in turn, recommends following regulations and industry standards. Despite the presence of code of ethics and regulatory guidelines, multiple ethical issues remain unresolved. This paper presents three of the example concerns faced by biomedical engineers. These are: 1) sufficient safety of the user (during utilization of the device), 2) need for clinical trials (that bears a possibility of the subject being harmed), and 3) confidentiality of the patients' information (which constitute a significant source to improve future versions of the device, or health service). Through a discussion of these examples it is revealed that the code of ethics in its current broad format, and the regulatory guidelines, are insufficient in helping out an engineer to make a safe decision and yet deliver a great device.

As a solution, the paper recommends inclusion of a more thorough and integrated study on the Code and FDA regulations, in biomedical engineering curriculums, as a way to equip biomedical engineering students with ways to resolve similar ethical dilemmas. This is based on a hypothesis of inadequate education of biomedical engineering students on handling ethical and regulatory issues in this field, through a general ethics course or module. This hypothesis was based on the result of screening biomedical engineering curriculums in twenty leading universities in the United States, and finding that only one of them requires a dedicated course on ethics for biomedical engineers. Moreover, this paper suggests improvement of the guidance from the Code of ethics and leadership from the related professional organization to reduce gray areas. It considered the completeness of the Code as a key to resolve ethical concerns. Upon scrutinizing each section of the existing Code from BMES and discovering the imprecise parts, also highlighted in previous literature, recommendations for improvement were provided[4, 5].

Dilemmas Prevail

Ethical concerns that the biomedical device design engineers often go through are uncovered in several research papers and articles[1, 4, 5]. Table 1 presents an analysis citing the three dilemmas in focus as mentioned in the introduction, and shows their coup through the Code. Possible parts of the code which best address them are quoted in the table to detect where the ethical gridlocks of biomedical device design still persist.

Table 1: Ethical dilemmas and guidance from the Code

Dilemma	Example of the Dilemma	Guidance[3]
Safety in the real use	• What safety level is ethically adequate to ensure before marketing? • Tradeoff between project time and safety assuring experiments	- "Use their knowledge, skills, and abilities to enhance the safety, health, and welfare of the public." ? The question of how much safety is expected to be ensured persists.
Clinical trial	• Could a simulation have been sufficient? • Is a clinical trial really necessary? • What if any harm is caused to the subject?	- "Comply fully with legal, ethical, institutional, governmental, and other applicable research guidelines, respecting the rights of and exercising the responsibilities to colleagues, human and animal subjects, and the scientific and general public." ? The question of responsibility of the experimenter for any damage caused to the subject persists.
Patient's privacy	• How much sharing of the patient's information is ethically justified? • Should the information be at all shared for further research? • If research is not there, how can better treatment be given?	- "Regard responsibility toward and rights of patients, including those of confidentiality and privacy, as their primary concern." ? The confusion of how much disclosure of patient's information is ethically acceptable, persists.
Overall (with reference to the above three)	• What justifies these efforts if the device performs unsafe in use, any harm is caused to the subject of the trial, or patient's information is misused? • Does the benefit of larger patient pool justify causing harm to one subject? Is each life not equally important?	- "Consider the larger consequences of their work in regard to cost, availability, and delivery of health care." ? The question - whether any harm caused to one person is acceptable if a large and good consequence for others is ensured, persists.

The first ethical gridlock is characterized in the design engineer's confusion of what safety level is ethically adequate, knowing that FDA considers any mistake to predict device

failure as "intentional"[6]. For instance, a patient with several complications was being carried to the intensive care unit[7]. The transport monitor was showing a normal blood pressure and heart rate which remained stable for longer than realistic for a critical patient. When the patient was reassessed manually, the actual numbers were found alarming. It was found noticing the small "D" on the monitor screen that the device had been left in the demonstration ("demo") mode mistakenly by the transport team. The demo mode is necessary for training and checking the device's functionality. The device certainly passed through FDA's licensing process and all the ethical obligations including patient's safety was considered in design. Yet, the unintentional small "D" was enough to cause life risk for that emergency patient. With some difference in design, operation of the device could be made inherently safer using bigger font, or auto prompt for mode change, or alarm for prolonged demo mode and so on. All these design possibilities remained as the liability of the engineers; neither the Code nor the regulation could filter out the device from their honest mistake. Instead, ethical concepts, like the "Good Works Model," requires a person to make judgment by going "beyond what is required by standards and codes" in order "to improve product safety, social health or social well-being"[7]. However, such model would go against time and resource constraints during device production, which are realistic challenges imposed on the design engineer, who is left with the question of how safe is completely safe, unanswered. At the end, the only guiding legal standard continues to be the regulation by FDA.

The second ethical gridlock pertains to concerns of damage that can be caused to the subject during clinical trials. BMES code of ethics guides engineers to "comply fully with legal, ethical, institutional, governmental, and other applicable research guidelines, respecting the rights of, and exercising the responsibilities to, colleagues, human, and animal subjects, and the scientific and general public"[3]. As such, the device design engineer needs to go through an unlimited list of research guidelines. Ethical research guideline, like Nuremberg Code states that "No experiment should be conducted, where there is a priori reason to believe that death or disabling injury will occur"[8], whereas for FDA approval, clinical test results are a must, rendering methods like simulation, which circumvents high possibility of harm to subjects, to be insufficient. Nuremberg Code allows exceptions in cases like experiments "where experimental physicians also serve as subjects"[8]. Nevertheless, it does not answer what the designer's responsibility should be if any unforeseen damage is caused to the subject. Instead, it gives rise to a new concern of whether endangering a subject, only because the experimenters are ready to accept danger for themselves, is justified or not.

The third ethical gridlock relates to the part of the Code which states that "engineers shall regard the responsibility toward and rights of patients, including those of confidentiality and privacy, as their primary concern"[5]. The worry remains regarding how much sharing of the patient's information is ethically justified and still useful for research[9]. Even courts of law are still struggling with this issue and the verdicts differ by location and time.

FDA Regulations vs. Code of Ethics

FDA's regulations and guidelines hold safety and effectiveness of a medical device as their primary focus, while requiring the device to contribute to human welfare in the area of healthcare[10]. This concept is aligned with the priorities of the relevant Code of ethics. Medical devices in the US can only be marketed upon FDA's clearance, or licensing, which essentially means a licensed device is safe and effective.

The challenges are: the multifaceted licensing process requires decision making on risk classification of the device, and on selection of correct application process (filing, premarket notification, premarket approval) to follow. FDA's review and approval also takes significant time, especially when the device does not have a similar product in the market, i.e. new inventions. Figure 1 presents a simplified summary of FDA's licensing process. The diagram does not detail the to-and-fro time needed for providing additional information to FDA, routing through the internal if-gates that can get an applicant maze in the loops of different routes.

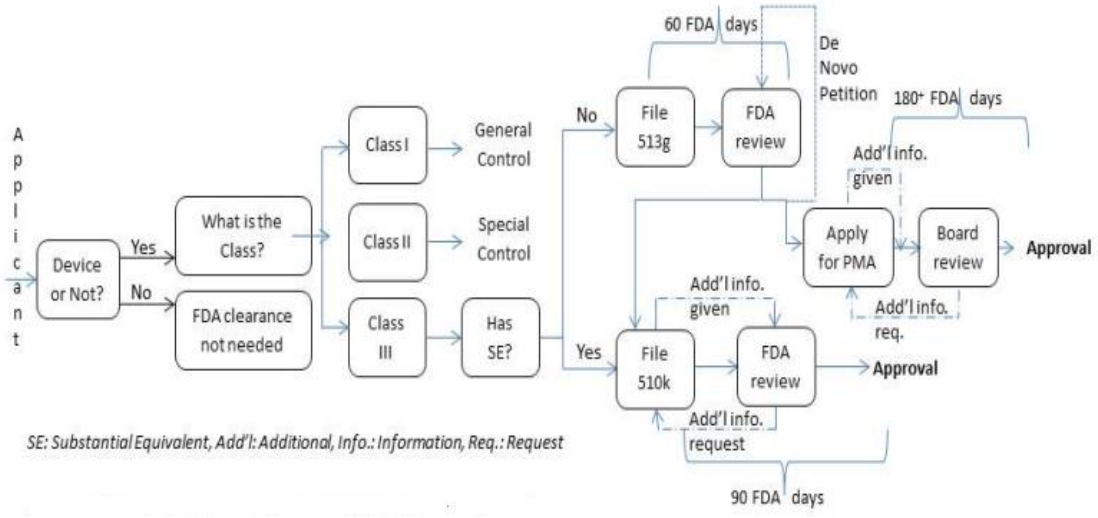

Figure 1: Flow diagram of the basic process of device licensing from FDA

A new invention needs nearly eight (8) months to be approved[11]. With the current competition, this time lag becomes detrimental to the inventor's market leadership. This results in less motivated manufacturers toward the noble spirit (safety and effectiveness) of the regulations. Manufacturers become more inclined to adhere only to the letters of the procedure to remain legal. It is not often difficult to present the new product as a similar one to an existing device and file the notification in a way that the equivalency criteria match for both[12]. Even without providing wrong information it lets the marketer to avoid the loops and delays in licensing.

This is an example of where practicality and functionality meets the supreme spirit and goal, but lengthy and complex process of licensing deviate the applicant from the ethical standard.

Improving the Biomedical Engineering Curriculum

As mentioned at the beginning, inadequate education of biomedical engineers in the area of professional responsibility and regulations is a reason for the ineptness in resolving ethical issues. Most engineering students receive ethics education through a dedicated course or other means as part of ABET requirements. However, for biomedical engineering students there is evidence that more is needed to equip them for their unique field. BMES was formed in 1968 and the latest revision of their Code of ethics was developed in 2004[5]. Biomedical engineering as a full-fledged undergraduate or graduate program is fairly new in the world of engineering. It

is found from surveying accredited biomedical engineering undergraduate programs offered in twenty leading universities in the US, as available on their websites, that most of them require students to complete certain credits of general education, but those courses are not a dedicated study on ethics for biomedical majors. Only Stanford University, among these twenty universities, has a dedicated course on ethics for bioengineering majors[13]. Georgia Institute of Technology mandates an ethics course for biomedical engineering majors from a given list of elective courses of humanities and social science.[14] John Hopkins University recommends a course in which ethical issues are discussed amongst economic, political, or social issues related to technology[15]. However, it was not possible to find out from the majority of the websites whether FDA regulations are consulted or integrated into the curriculum. Some universities incorporate the regulatory side of medical device design in a part of the curriculum that is not connected directly to the study of ethical issues. For example, In Grand Valley State University, the licensing requirements are consulted as a part of a medical device design course[16]. Also, the University of California at Berkeley discusses basics of the regulations as part of their course named Structural Aspects of Biomaterials[17, 18].

Based on the short history and the investigation on the programs, it appears that this is the right time to integrate the Code in conjunction with the ethical perspective of the regulations as part of biomedical engineering education[19]. Addition of these two in the curriculum will facilitate more reviews of the Code and the regulations which will eventually help incorporate the experiences of the practitioners' in the ethical guidelines and make these more fulfilling. The benefit of consulting the Code and the regulatory guidelines in classrooms is it allows fresh ideas, without commercial interest, to flow in and interact with the ideas of the experienced ones. Classrooms also work as a good place to test new ideas or proposed modifications on hypothetical cases. It provides a forum to demand the changes required in the Code for it to be more fulfilling in addressing the design engineers' ethical dilemmas. In the process, the essence of both the principals (the Code and the regulation) becomes implanted in the emerging biomedical engineers' mind. It may ultimately prevent them from straying away from the spirit of the rules and enable them to come up with creative solutions to the gridlocks.

Improving the Code in Relation to Legal Standards

As hypothesized in the beginning, impreciseness of the Code is a contributor in ethical gridlocks. Screening the Code revealed its reach to the ethical priorities at a broader level, leaving a number of gray areas for dilemmas to persist. As it guides to follow regulations, the regulatory requirements need to be synchronized to better address common ethical dilemmas faced by the medical device design engineers. As a step towards improvement, the Code needs more detailing and the regulations need to be more practical while preserving quality.

This harmonization can be achieved using multiple small steps including reviewing the Code and the regulations frequently (e.g. annually), among experts from all related fields of biomedical device design, education, and licensing. Frequent reviews of regulations might be occurring, but the continuously evolving ethical issues can be better resolved using this integrated approach in the reviews. BMES can take the lead in facilitating this effort as most professional engineering organizations are currently doing through handling initiation and guidance of codes and standards related to their relevant areas. The regulatory body (FDA) should consider a more inclusive approach to reviewing the rules and the professional society should take a more active role in advising the regulatory body.

For immediate tuning of the Code, some explicit guidelines and themes can be incorporated in the different sections of the Code as discussed in the following points:

1. **Professional Obligations**: Safety of the user or patient needs to be emphasized as the highest priority. The Code from National Society of Professional Engineers can be followed for wording[20]. References should be made to the FDA regulations and the higher ethical calling of professional beyond legal requirements.
2. **Privacy issues in relation to product improvement**: Some guidance is needed regarding sharing of patient's information for research on device performance. Some limit is needed to be mentioned for the engineer to be ethically clear about adequate safety considerations. For instance, defining appropriate failure mode could be set as the engineer's acceptable responsibility.
3. **Professional responsibility:** The Code needs to be more explicit on unknown consequences that a design engineer reasonably cannot predict. It can hold them responsible for gross negligence, but needs to be a respite for practically unpredictable results.
4. **Research Ethics:** Addition of some minimal research guidelines that must be followed in biomedical engineering research, as an appendix to the Code is required to equip researchers with the basic ethical guidance to start with. In addition, a guideline needs to be in the Code on what to be considered as research and on whether it will be in the scope of the mentioned appendix or not.

Conclusion & Recommendation

This paper presented three examples of ethical issues lingering with biomedical engineers in spite of the existence of related regulations and a code of ethics from the relevant professional society, BMES. Studying these issues shows that education of biomedical engineers as while in college is inadequate and has clear room for improvement. The greater forum for familiarizing and training up the rising biomedical engineers in solving ethical issues as well as breeding innovative solutions to the problems is recommended to be the classrooms. Studying the Code, integrated with regulations is suggested to be added as part of the biomedical engineering curriculum. Case studies and other classroom activities can be developed and tested for their effectiveness in enabling engineers to make better ethical choices.

In addition, the Code of ethics of the BMES takes a broad approach that challenges its practicality. Lack of detailing of the Code adds up to the challenges faced by biomedical engineers. The Code can be improved further to provide more guidance to reduce areas of ethical dilemmas like the ones discussed specifically in this paper. It is recommended that the BMES code of ethics include more explicit statements addressing the higher calling of the code compared to legal and regulatory requirements while emphasizing the close agreement between the code of ethics and the spirit of regulations. FDA's device licensing process can be streamlined further for a more practical utilization and ease of understanding. This will make it simpler to follow and less time consuming.

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