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AP Language

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Biomedical Engineering

In freshman year of high school, two of my classmates and I decided to venture into the world of the Emory University Radiology Department. The professor we worked with introduced us to the idea of breast phantoms, or representations of human breast tissue, that are used to test new imaging devices prior to being tested on humans. However, these phantoms cost about $1000 each, making experimentation rather difficult. For our science fair project, we strived to produce breast phantoms using oil and jello to represent the glandular and adipose tissues found within human breasts. After testing our home made phantoms with a mammography machine, we found that our results were relatively similar to that of real breast tissue. After reaching the state level of competition, we began to think of continuation projects- perhaps creating larger phantoms that were appropriately shaped so they could be tested among other imaging devices, such as Emory University’s relatively new breast-CT scan. Although this portion of our project was never fully completed, I began to wonder how new devices were created by scientists and how they were tested before being used on humans. What did it take to fully eliminate the risk factor involved in newly engineered technologies? This was the first step I took towards the path of biomedical engineering, and I’ve been on that path ever since.

Medicine has always attracted me- as a curious biology student and helper of mankind, I’ve known that I want to pursue a field that is related to medicine and health care. When I discovered the field of biomedical engineering, there was a sudden relationship between a project

I had devoted a year of my life towards, and something I've always wanted to pursue as a career choice. It was the combination of medicine and bettering the quality of life for individuals, and creating new technologies that can cause a progression in the practice of medicine. It was biomedical engineering. Although this is a perfect unification of two fields in my eyes, many obstacles arise; ethical and regulatory concerns become a major issue because the newly engineered technologies have an immense risk factor since human lives are at stake. Despite this challenge, biomedical engineering allows individuals to become specialized in both medicine and engineering, allowing them to become the 'hybrid engineers' that can tackle the obstacles of biomedical engineering.

Biomedical engineering is essentially applying engineering skills to solve health care issues and medicinal problems (Enderle). Therapeutics and monitoring is included in this. Recently, biomedical engineering has become its own discipline, originating from biotechnology and bioengineering, with current branches ranging from tissue engineering to clinical engineering. Regardless of the specialization of engineering, whether it is chemical or genetic, for example, all aspects of the engineering field are specifically related towards medicine and medical technologies. This can be evidenced by the major classifications with biomedical engineering, including tissue engineering, genetic engineering, neural engineering, clinical engineering, and medical devices. With all biomedical advancements, however, come a plethora of ethical considerations and regulations that biomedical engineers must readily withstand.

It would be a lie to state I have always dreamt of being a biomedical engineer; to be honest, the details of the profession were slowly revealed to me as each informative article was read for this paper. Overall, I am most compelled by the field's ability to incorporate both medicine and engineering into a hands-on discipline that is not completely based off of research.

Although researching other biomedical technologies and their functions is an extremely important part of the field, "biomedical is extended to both researching *and* designing technologies so they can be used in the practice of medicine" (Brey). The compilation of research directly influences the design and alterations done to each technology, and biomedical engineers have the flexibility of both conducting research and creating new technologies. This allows for the production of more efficient technologies because biomedical engineers can utilize their awareness of previous technological designs assess the necessary improvements that need to be made to future designs. These changes can result in the reduction of costs by using different materials, an increase in safe practice of the machine, an increase in the productivity or practicality of the technology, or an increase in convenience in utilizing the biomedical technology (Fielder).

One of the most fascinating classifications of biomedical engineering is tissue engineering, It is these types of engineers who are able to create an artificial pancreas that has the ability to regulate insulin levels and artificial urinary bladders that have been transplanted into humans numerous times. Tissue engineering has many ethical issues involved, however, due to its use of plant and human cells. This is unethical due to the crossing of two different types of species. Additionally, when embryonic tissue is used, human embryos become destroyed, and that is unethical because that is similar to that of abortion. Tissue engineering also faces many ethical questions regarding donors Overall, tissue engineers are making remarkable developments each day that can improve the quality of many lives (Varello).

Genetic engineering, which is another classification within biomedical engineering, involves innovations in modifications of various genetic structures. An example of genetically engineered technology is artificial human insulin by using bacteria. Overall, genetic engineers focus heavily on somatic cell therapy. Today, it is agreed that somatic cell therapy is ethical when it is used to treat serious diseases. Germline engineering is a specification within genetic engineering that is currently being studied, which is altering genes found in egg cells or sperm cells, for example. Currently, germline engineering is not being used therapeutically. It is still raising many ethical concerns. The biggest concern is human enhancement, as it is with all different types of engineering (Enderle).

Furthermore, neural engineering is a category of biomedical engineering that is modifying different parts of the nervous system, including the central nervous system and the peripheral nervous system as well. They help create connections between devices that will allow an advancement in communication and increased functioning. Examples of technologies created by neural engineers includes the development of brain implants, as well as the creation of brain-computer interfaces that make the exchange of signals possible. As neural engineers create new technologies, they are typically tested on animals before being tested on humans. The extensive use of animal and human research is one of the primary ethical issues surrounding not only neural engineering, but biomedical engineering as a whole. Because neural engineers have the ability to restore functions of neural systems, their ability to enhance motor control and other functions in the brain has also been an issue of tremendous controversy. Another controversy is that neural engineering can take away from personal identity by adding an ample amount of artificial material and devices in one's brain. (Varello).

All of these types of biomedical engineering are essential to the progression of the medicinal field. However, without clinical engineers, these new technologies would not have the ability to be implemented in hospitals and other clinical settings. Clinical engineers work with supervising and monitoring the use of technology in the clinical settings they work at. They play a crucial role in hospitals and clinical settings by developing cost-effective approaches for using new technologies. Clinical engineering is one of the only branches of biomedical engineering that does not have to overcome ethical issues because clinical engineers do not focus on the development of the technologies, but their practice and implementation after the technology has previously been deemed safe. However, clinical engineers typically work with regulation agencies in order to discuss safety issues and accepted medical practices. By doing so, they allow the new technologies become available to patients for use in monitored, clinical settings (Fielder).

The most broad category of biomedical engineering is not a specific field of biomedical engineering, but rather a compilation of all of the medical devices that the variety of engineers develop. This ranges from infusion pumps to prosthetics, from imaging devices to implants, and beyond. As long as it is used for diagnosing or preventing a medical condition, it falls under the category of a medical device. An example of a medical device that is commonly used includes imaging devices including X-rays, MRI's, and ultrasounds. The use of medical devices does not raise as many ethical issues as some fields of biomedical engineering, although the extensive use of these devices on a particular individual does. The use of prostheses and implants raises many questions. Additionally, if a human becomes too reliant on medical devices, it is possible that humans can reach a point where they are mostly artificial. This could result in the decrease of human like qualities among humans that have lots of medical devices planted within them. Although this is one of the deeper ethical issues in biomedical engineering, they must also be ready for clinical trials. Although the conditions that must be met for ethical and responsible testing of new medical devices are consistent, it is questioned how thoroughly these devices should be tested before they become available for use. In terms of biomedical imaging, safety is not as much of a concern considering we have made tremendous progress in terms of imaging safety. However, there are concerns that our imaging has become *too* good, specifically in brain imaging. Although this is a frightening possibility, is not currently a major issue because such extensive technology is only available to the most elite imaging specialists. However, the possibility does remain. Additionally, diagnostic imaging is not a point of concern for reasons that our technologies are not safe or effective enough, but that they may be too effective. This could result in minor imperfections and defects being considered new-found diseases, leading to over-diagnoses of mundane issues.

When conducting research, many scenarios and case studies were discussed. One example is that of Terri Schiavo. She suffered heart failure and after a year of visiting rehabilitation facilities and nursing homes, was diagnosed as an irreversible persistent vegetative state. Her husband made a petition to the Florida courts to take her off of her medicinal device, a feeding tube, after a doctor confirmed she was brain dead. However, the parents fought this and believed it was unethical for her feeding tube to be removed because it would result in her death. After 15 years of an ethical debate, Terri Schiavo died after her feeding tube was removed for a total of two weeks, as her case was being discussed at the Supreme Court. (Kalichman). Another case study that was of the artificial heart, ‘Jarvik 7’. People decided the first recipient would have to be someone sick enough that they would be dying soon. This caused a series of ethical debates in the early 1980’s because this artificial heart had no guarantee of working and also posed many health risks. Although the transplantation of artificial organs with such a high risk factor is not often debated today, biomedical engineers must still face the immense regulations posed by the FDA and conquer the ethical issues that can hinder clinical testing.

In order to get a better understanding of biomedical engineering and the types of newly engineered technologies, I interviewed Dr. Suman Das, a bioengineering professor at Georgia Institute of Technology. He has worked specifically with tissue engineering, and was able to provide me with information on recent advancements in tissue engineering. According to him, "[Tissue engineers] have now mastered many aspects of progression in tissue engineering. Clinical trials are also used for reconstructing tissues. Believe it or not, tissue engineers work with blood transfusions and advancements in the dental industry too" (Das). He continued on to stress the importance of accuracy of biomaterials that are used for tissue engineering. Many things must be considered, including pore size within the biomaterial that is relative to the specific functioning of the artificial tissue. When asked about how engineered tissues are tested, Dr. Das emphasized the time it takes from the moment a new technology is designed to the time it is readily available for patients in a clinical setting. Many technologies do not even reach patients because hospitals either choose not to invest in certain technologies. Additionally, a considerable amount of testing has to conducted for each technology before its usage can be administered on humans. At the end of the interview, he made one final point: although biomedical engineering is considered a 'new' field, it has been around since World War II. So, although biomedical engineering is making massive progress in all aspects, a breakthrough technology is not being developed on a daily, weekly, or even yearly basis. Instead, tons of research is conducted, numerous models are made, and various designs are discussed, until eventually, a breakthrough will occur.

As Dr. Das was closing the interview by reminding me of the slow progression of biomedical engineering, one of my favorite movies came to mind- *The Pursuit of Happyness*. In this movie, Will Smith plays a character that is trying to make a living off of selling a portable bone-density scanner to various clinics and hospitals. However, he is not successful in doing so because doctors continue to think they are an unnecessary expenditure. Although these scanners produce better images than X-rays, the enhancement is not significant enough to spend such a large sum of money. This is very relatable because technologies can be modified and enhanced, perhaps easily, but in order to reach a point of medicinal use, the enhancement must be significant and the technology must also be cost-effective. Therefore, biomedical engineers must not only produce better technologies, but must find ways to do them in cheaper ways that will allow easy accessibility for patients.

As a future biomedical engineer, I hope to contribute new ideas and innovations. Although that is the goal of all biomedical engineers, I feel that my persistence, curiosity, and determination will lead me to making remarkable innovations. While conducting my research, the main component I was unable to adequately research was the usage of clinical trials in testing various medical devices. The exact process between creating a successful machine and conducting the first test on a human is not readily available, making this portion of my research extremely difficult. I have come to understand that it depends on the type of device and the risks involved, although no specificities were given. Therefore, I would like to interview individuals who work on implementation and clinical testing of newly engineered technologies.

When first beginning research, I was not sure what I would learn or if any specific part of biomedical engineering would interest me. However, after conducting a tremendous amount of research, I have learned that I find an extreme interest in clinical engineering. Working with regulatory agencies, hospital personnel, and other health care providers would be my strong suit because I would have the ability to implement, monitor, and supervise a technologies that my fellow engineers have spent so long engineering. In the meantime, I may continue my unfinished science fair project and re-connect with the professors I closely worked with for a year and a half; it's quite possible that their breast-CT scan is effectively being used on humans at this point. Overall, the research I have conducted has helped pave my otherwise broken path to biomedical engineering. It has helped me realize that this field is one that not only suits my personality, but will be something that I can enjoy doing because many aspects of it not only interest me, but bring out the curious individual within me. Until then, I will look towards furthering my knowledge in the field so that I can possibly be the valedictorian of Georgia Tech's Biomedical Engineering Program.

Works Cited

Brey, P. (2009). ‘Biomedical Engineering Ethics.’ Eds. Berg-Olsen, J., Pedersen, S., Hendricks, V.(eds.), A Companion to Philosophy of Technology. Blackwell.

Das, Suman. Tissue Engineering." Personal interview. 12 May 2012.

Enderle, John, and Joseph Bronzino. Introduction to Biomedical Engineering. 3rd ed. Burlington: Elseveir, 2012. Print.

Fielder, J. (2007). Biomedical Engineering Ethics. Morgan & Claypool.

Kalichman, Michael. "The Schiavo Case: Ethics and the End of Life." North County Times. 27 Mar. 2005. Web. 12 May 2012. <http://www.nctimes.com/news/opinion/commentary/article_0857904a-9f72-5ab8-a4b7-fc21d26dd52e.html>.

Varello, D. (2007). Biomedical Ethics for Engineers: Ethics and Decision Making in Biomedical and Biosystem Engineering. Academic Press.