ETHICAL ISSUES REGARDING TISSUE ENGINEERING FROM AN ENGINEERING PERSPECTIVE

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IMPORTANT OF ETHICS IN ENGINEERING

Every profession today has a code of ethics which are used to hold their members to the highest degree of integrity and professional conduct. In engineering the observation and adherence to these ethics is of the upmost importance. Without a code of ethics to follow engineers could endanger the public and damage their profession’s reputation [8]. Biomedical engineers must take special consideration in following their ethical codes due to the subject field of their research, and their close interaction with patients [1]. Tissue Engineering is one of the forefront technologies studied by biomedical engineers today. Because of the nature of tissue engineering, researchers face several unique and complex ethical issues. Aside from general ethical issues, tissue engineering faces several ethical dilemmas on topics such as the incorporation of stem cells in research, patient access and availability, patent claims, and consequences of their research [9].

ENGINEERING SCENARIO

I am an engineer working for Tissue Engineering Incorporated. I am currently in charge of a design team working to develop an artificial lung. In 2014 we began working with three dimensional printing to develop scaffolding which would induce applied stem cells to grow into a mature fully functioning adult lung. In the spring of 2015 we successfully developed a scaffolding matrix which facilitated the growth of lung tissue. We based most of our design off of experiments conducted in 2014 by a research team at Harvard. They pioneered the way for the use of ink polymers as replicas of blood vessels [3]. This type of system is required to provide the tissue cells with enough nutrients and waste disposal [3]. In the fall of 2015 our artificial lung was approved for clinical trials.

After two years it was approved for access to the general public. Those two years were very rocky however. Because a device such as ours has never been created before the Food and Drug Administration, which oversees the review and approval of all medical related devices, drugs, and biological products, does not have a classification for our product [11]. Due to increasing financial costs of our trials my firm recommended I take advantage of the FDA’s lack of familiarity with our type of product to classify it in a way which would eliminate some safety tests in order to streamline our trial period. Currently the FDA classifies tissue products designed to provide structural support as devices, while products which provided a more regenerative effect would be categorized as biologics [11]. Since our artificial lung fulfills both categories, we have the option to classify it as either a device or a biologics. Since devices face much less regulation and safety requirements as biologics due [11], my company advised me to report it as a medical device.

As our company began to prepare for wide scale production, I was informed that our artificial lungs would not be accessible to everyone. My company had decided to limit distribution only to patients who lived within North America or Europe, as well as stipulating that patients requiring a lung transplant would be treated in an order based on the nature of their problem. In other words patients who required a lung transplant as a result smoking or other abuse would be placed behind patients who suffered a lung injury/disease from outside of their control. These limits on distribution are only known internally, and we have been instructed not to mention these limits for patient access outside of our office.

THE ETHICAL DILEMMAS

As the head engineer for the design team responsible for this product I faced several ethical issues throughout the process. The first issue arose during our initial experimentation stage with the use of stem cells. Stem cell use in research has been a controversial topic for several decades now. There are two main types of stem cells that are used in research [4]. Embryonic stem cells, which are extracted from human embryos and often result in the destruction of the embryo, and Adult Stem cells [4]. As expected the main issue arises with the use of embryonic stem cells due to how they are obtained [4]. My justification for the use of stem cells during our research and development stage was that they would not be necessary for our final product. This is because artificial organs grown from cells independent of the patient possess a high probability of being rejected by the body, which is one of the most prevalent issues with organ transplants today. Without being grown from the patient’s own cells the artificial lung has a high probability of being identified as a foreign substance by the patient’s immune system and attacked or destroyed.

Another issue arose during the clinical trials of our artificial organ. During this period our product had to
undergo hundreds of tests for safety, effectiveness, durability, and sustainability. Due to its intended purpose the FDA would most likely create a new product classification which treat it as both a device and biological. This means that it would most likely be required to undergo all mandatory tests for both devices and biologics. Instead we classified it as only a device which means that some tests which relate to its non-medical properties such as storage capability, travel durability, and construction time that biologics undergo were not addressed. When dealing with less invasive devices, such as prosthetic limbs, these tests are often optional and avoided because they would not make a significant impact in the final product. David Smith published an article in Periodontology 2000, an academic journal, in which he addressed how new products such as are cannot easily be represented in the FDA’s current classification system [11]. Looking back I regret my decision to skip performing these tests. Without the results of these tests our company does not know how to properly store or transport the artificial organs for extended periods of time. This means that we could possibly supply a patient with an artificial lung which had degraded beyond the point of acceptable performance. Apart from the legal ramifications of this, I would have tarnished the reputation of both my company and my research field. This could lead to less support for future experiments and innovations in tissue engineering from both the general public and potential investors.

The largest issue arose after our product had been approved for use by the general public. The stipulations limiting patient access immediately appear to violate both the National Society of Professional Engineer’s, and the Biomedical Engineering Society’s codes of ethics. These codes call for providing for the welfare of the public, honesty, and responsibility towards their patients [1]. However upon further inspection this issue is far more complicated. If these artificial organs served to eliminate all lung related diseases including cancer, millions of people would be saved each year. According to the World Health Organization over 1.59 million people die from lung cancer each year around the world [13]. The Nation Hear, Lung, and Blood Institute of the U.S. Department of Health & Human Services also notes that approximately 9% of all deaths in the United States are due to lung related issues excluding cancer [7]. As our world is already facing unprecedented population growth, the additional growth compiled from lives saved by our artificial lungs could cause an even bigger issue. By first servicing patients who incurred a lung injury/disease from beyond their control we are potentially attempting to quantify life and place the life of one person above the life of another. While this seems unethical, this practice is already adopted in current systems such as the organ transplant system. Additionally, the facilities needed to culture and grow the artificial lungs are extremely expensive to construct and maintain. While this is not an issue throughout the North America or Europe, other areas of the globe such as Africa and South America may not possess such facilities. Combined with the constant turmoil and high levels of corruption in some of these areas, providing such a revolutionary product might grant additional violence as faction fight over either the facilities or the artificial lungs themselves. Despite

The dilemmas present throughout my scenario depict real issues that could arise for an engineer involved in tissue engineering. Some of these issue are more complicated than others, however any problem or issue which could be considered even moderately unethical should addressed in order to preserve my individual and profession’s integrity, dignity, and reputation.

**GENERAL ETHICAL ISSUES IN ENGINEERING**

All Engineers face similar ethical issues regardless of their field of research. The National Society of Professional Engineers’ code of ethics is composed of six canons: “Hold paramount the safety, health, and welfare of the public”, “Preform services only in areas of their competence”, “Issue public statements only in an objective and truthful manner”, “Act for each employer or client as faithful agents or trustees”, “Avoid deceptive acts”, and “conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession” [8]. These canons are there to provide a guide to engineers when faced with a potentially ethically compromising situation. These situations can range from disregarding a safety policy, to bribery for a public contract, misrepresentation of data, or endangering the general public. In 2011 the Association for Practical and Professional Ethics held their annual meeting at which they discussed current ethical issues, and ways to train engineers to avoid these issues [2]. One of their main topics of discussion was the BP oil spill in the Gulf of Mexico [2]. The engineers involved with this incident violated several of the canons listed above by falsifying their reports and ignoring safety precautions [2]. One of their justifications was that they had deemed their decisions to be based around an “acceptable risk” [2]. Since engineering is filled with so many grey areas such as this, the decision will ultimately be up to the engineers working on the project. This is why having a code of ethics to follow is so important. It provided guidance to engineers when they are faced with difficult scenarios.

**ETHICAL ISSUES IN BIOMEDICAL ENGINEERING**

Within engineering, biomedical engineers face several ethic issues unique to their field. Many of these issues arise with regenerative medicine such as tissue engineering. All biomedical engineers must adhere to the biomedical engineering society code of ethics. This code places

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additional emphasis on dealing with animal/human patients and healthcare because of the close ties biomedical engineering has with those areas [1]. In the scenario depicted I violated my ethical obligations towards providing for the general public’s safety and preparing honest research reports. I also violated these obligations by refusing to provide our product to patients in certain geographical locations, however when taking external factors into consideration it can be deemed that our product has the potential to do more harm than good in those locations. When faced with an ethically compromising decision all biomedical engineers should use their ethics codes for advice on how to proceed in a manner that will maintain the honor of their and their professions reputation.

ETHICAL ISSUES IN TISSUE ENGINEERING

Tissue Engineering is unique within biomedical engineering because it draws from a multitude of different fields. In its most basic form it is simply creating materials and structures which can either replace or facilitate the growth of organic tissue [3]. It is divided into two main focus areas. The first being the design of scaffolding, with the other area being the polymers which make up the scaffolding. Throughout the years scientists and researchers have discovered several methods of constructing scaffolding such as phase inversion, three-dimensional printing, electrospinning, and Stereolithography to name a few [3]. Some ethical issues currently in tissue engineering are the use of stem cells, future patient access, and patent claims. Many of the scaffolding methods listed above use stem cells to grow their tissue samples. Because most embryonic stem cells are derived from human embryos (which are destroyed in the process) there is also substantial ethical debate over whether or not they should be used for research and in healthcare [4]. Similarly if tissue engineering proceeds to develop artificial organs, it will need to be decided who they will available for.

Another case study done by Texas Tech University depicts a hypothetical case where an engineer faces a situation where certain tests have not been run on his project [6]. This case address my team’s decision to bypass certain tests in order to expedite our time in clinical trials. This issue is problematic because although the tests do not directly pertain to the products function, the gravity of our product and the potential risks its malfunction could cause dictate that all precautionary measures should be taken.

Stanford’s biodesign department theorized a case where access to a medical product was restricted based on geographical location [10]. This case bears many similarities to my situation because my company wants to limit patient access based on geographical location and current health. It is very obvious here that this would be an ethical dilemma for an engineer because their code requires them to provide for the welfare of all the public, not just a select few.

SUMMARIZATION OF CONCLUSIONS

This hypothetical scenario has provided me a lot of insight into how vital ethics are to engineers. I was not expected so many ethical situations to arise from one scenario. I would highly recommend that all engineers familiarize themselves as much as possible with their respective ethical codes as well as analyze several case studies. Without this knowledge engineers may find themselves in a situation which is forcing them to compromise on some of their ethics. An engineer with a strong knowledge and background of these ethics would be able to handle these issues appropriately or circumvent them entirely. With all engineers adhering to the ethical guidelines established for them, we will continue to grow and advance our profession and bring countless new technologies and innovations to the world.

CASE STUDIES RELATING TO THESE ETHICAL ISSUES

There are several case studies that pertain to the dilemmas outlined in my scenario. Dr Thomas Murray analyzes a case where issues arise over the source of a tissue sample [5]. This case relates to the use of stem cells in our research since our required stem cells to develop a fully functional final product people may be opposed to the results of the research. While the author does not provide a resolution to this problem, one can extrapolate that he does not appear to be in favor of research which uses objectionable tissue sources.
REFERENCES


ADDITIONAL SOURCES


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