BIOPRINTING ETHICS: MAKING THE RIGHT DECISION

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THE TRIAL PHASE OF PRINTING ORGANS

It is 2022 and I have joined a research team after receiving my Master’s degree in bioengineering from the University of Pittsburgh. The organization I am now working for is BioTissue Tech, an organization aiming to design and create functional human tissues. The group I am involved with is focusing on three dimensionally printing organs. My team is exploring the possibilities of using biomaterials and stem cells to recreate organs specific to a single person’s cells. Once marketable, this technology will diminish the need for the organ transplant list and greatly reduce the number of organs rejected by the body since they will be engineered specifically for the individual.

My team has successfully printed functioning organs and we are currently in the trial phase. Our research is now at a standstill because we ran out of funding. One of the biggest issues with bioprinting is cost. Not only are the machines themselves expensive, but it also takes a lot of money to run them and pay for materials. The initial research grant we received has just run out. In order to move to the next phase and release this technology to the market, we are required to conduct the procedure on at least 150 patients for the trial. The trial, as of now, has a 98 percent success rate. The problem is, we have only performed 135 of the required 150 procedures.

Three dimensional printers also take a long time to create the products. Robert Olson from the Institute for Alternative Futures explains “The slow speed of 3-D printers is a major constraint on their use in mass production. Most items take hours or sometimes even days to print. Speeds will increase, but unlike desktop paper printers, which have become faster, the speed of 3-D printers is limited by physical constraints” [1]. Even if we find more funding, we are already behind schedule.

Another large issue arising in bioprinting, and three dimensional printing as a whole, is the threat of intellectual property theft. Gartner, an information technology research and advisory firm that provides technology related insight, predicts that “in the next 3-4 years, 3D printing will result in the loss of at least USD 100 billion per year in IP globally” [2]. The major concern with theft is that three dimensional printers are available to the public, so anyone will be able to recreate products already on the market and products that are still in trial phases with the correct specifications and knowledge. One would think that gaining this knowledge would take a lot of time and effort, but the internet possesses a wealth of information that is accessible to anyone who knows how to use Google. If somehow my team’s research and techniques were leaked to the public before we are able to get enough funding to complete our trials, all our hard work could go to waste if another company has the money to do the trials we could not perform.

The leader of our project is pushing for the rest of our team to falsify the data and claim we completed all of the required trials. If we do not release our research soon, we are at a very high risk for intellectual property theft, but if we falsify the data we could potentially be hurting future patients and I would have contributed to illegal fabrication of research data. I help falsify the data or attempt to find another way to fund the project?

FOLLOWING THE CODES OF ETHICS

The two codes of ethics that would help in making this decision are “The Code of Ethics for Engineers” created by the National Society of Professional Engineers and the “Biomedical Engineering Society Code of Ethics”. The National Society of Professional Engineers (NSPE) writes in their code of ethics: “Engineers shall be objective and truthful in professional reports, statements, or testimony. They shall include all relevant and pertinent information in such reports, statements, or testimony, which should bear the date indicating when it was current” [3]. Falsifying data in our report would go against the code of ethics for all engineers. If one engineer violates the code of ethics, they could be endangering hundreds, even thousands, of lives. After one person disregards the code of ethics, there is no stopping all others to disregard them as well, possibly putting even more people in danger.

Along with the national society setting a code of ethics that contradicts intentions of the leader of our group, the Biomedical Engineering Society (BMES) states in their code: “Biomedical engineers involved in research shall 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” [4] and should “Publish and/or present properly credited results of research accurately and clearly” [4]. Our responsibility in doing this research is to save lives. A minimum number of trial patients is required in order to decrease the possibility for a bad outcome. If we release too quickly and people die from our lack of concern for the rules, their deaths will be our responsibility and they will be on our conscience. Creating this fake data also constitutes as lying, which is considered morally wrong and contradicts the code above concerning publishing properly credited results.
THINKING OUTSIDE THE BOX

The codes of ethics from both the National Society of Professional Engineers and the Biomedical Engineering Society are helpful resources when making an ethical decision, but we do not always follow a set of rules in order to make decisions. Whenever I have to make a big decision, or even a small one, the first person I turn to is my mom. Reaching out to a person who has your best interests in mind will always make a great consultant. This person could be a parent, a sibling, or a best friend; the only thing that is important is that you trust them and they want the best for you.

I always go to my mom for advice for making decisions since I am a very indecisive person. It also helps that she knows the way I think and is able to help me think logically if I am becoming very emotional about a choice I have to make. I am the type of person to overreact to everything, especially while debating important, life-changing decisions. The most important piece of advice my mom has ever given me is: “take a step back and relax” [5]. When you look at a situation form all points of view/angles, sometimes it becomes very clear as to what choice to make.

Another outside perspective I find very useful is my father. When making ethical engineering related decisions, my father is my go to source since he is an engineer as well. Going to someone who has been in the same, or similar, situation can be helpful because they have already had to make these difficult decisions. My father always says: “go with your first instinct; it is usually the right choice” [6]. An engineer has to find resolutions to large problems on a daily basis. If you trust yourself, these resolutions will be significantly easier to determine.

One final tactic I use to make decisions is a pro and con list. This method is helpful if it is physically written out in order to visually see if the consequences of an action are worth it. In my situation, the positives of falsifying the data would be that we would not be vulnerable to intellectual property theft, there would be no need to find more funding, and our product would create an immediate influx of cash. On the downside, faking data is illegal and morally wrong. It also opens us up to a huge possibility of problems with the research itself because without finishing the analysis, we do not know all of the consequences of our procedure.

A positive vs negative list is always a good way to plan out a resolution. While making the list, it may be evident which outcome would have the most benefit. Also, the list could also help with coming up with different solutions and ways to compromise without giving up your integrity.

WEIGHING MY OPTIONS

The leader of our research team is pushing for all our members to get on board with creating false data. In this situation I have two options: falsify the data and go along with the leaders’ plan or attempt to find another source of funding for the project.

Fabricate False Data

The simplest option at this point in time seems to be going along with the leader and publishing false data. One of the pros to choosing this option is the inflow of cash that would immediately follow the release of the research. With this money, theoretically, we could go back and complete the trials and correct our data. Another big reason we should publish as soon as possible is to help third world countries. Gartner says that releasing three dimensional printing would allow for “life-changing parts and products to be built in struggling countries” [2]. Along with saving lives in the United States and other developed countries, we would be able to help countless people in underdeveloped countries by improving their healthcare.

As I mentioned earlier, intellectual property theft is a growing concern in three dimensional printing. If my team were to publish our research now, we would not run the risk of another company stealing our ideas and releasing the research as their own. Other companies may have access to more funding than we were given and could run all required tests before we are even able to find another source of money.

The last positive outcome falsifying data would yield is the ability to save more lives and to start saving them sooner. Since all the procedures we have completed so far have resulted in a 98 percent success rate, our hopes are very high for the future of biologically printing organs. One could argue that the miniscule number of tests we have not done yet would not result in anything dissimilar to the current findings.

Unfortunately, there are many disadvantages to choosing this option. First, not completing the number requirement of trial patients and publishing false data is illegal. There are very grave consequences if we are caught. Second, everything about this option goes against the set codes of ethics for all engineers and for biomedical engineers. Lastly, going down this path contradicts my morals.

Find Another Option

Falsifying data may seem like an easier in the short term, but finding another option may be a better way to go about coming to a conclusion. One pro of choosing to find another source of funding is that it is morally right; you would not need to lie and cover up the problems with the data. Also, this option follows the codes of ethics mentioned earlier. Another reason this is a feasible option is it leaves no risk of getting caught by the authorities because no illegal acts would be committed. Lastly, if we follow the guidelines and complete all the procedures, we have less risk of hurting future patients. There is a possibility that there are flaws in our design and the patients we have operated on so far have not seen any side effects, but the plausibility is still there.
Despite the fact that this option seems like it has less risk, there are still downsides to choosing it. We are already behind schedule with our research and attempting to find more funding will require a lot of time we cannot waste and effort that could be used to finish our research. Also, the longer we take to continue the project, the greater risk we are at for intellectual property theft. Lastly, there are other companies researching similar technologies and we cannot afford for another team to publish studies similar to ours before our trials are complete.

**DRAWING CONCLUSIONS**

Making a decision in this scenario could be a difficult task for most, if not all, engineers. After analyzing both the positives and negatives of my options, I would most likely chose to find another source of funding. Every portion of the first option contradicts my morals. Along with the second option being the right thing to do, I do not believe I could live with the guilt if future patients died because I neglected to finish the required research. Even though the second option requires more effort and time, it has no life altering consequences. The consequences of the first option are far too great if I am caught illegally publishing false data. Since every person is different, another engineer may choose the first option, or possibly even come up with another alternative that does not require as much time and is morally right.

**RECOMMENDATIONS ABOUT MAKING ETHICAL DECISIONS**

The best piece of advice I can give about making an ethical decision is to weigh your options carefully. The more closely you examine your alternatives, the more evident the correct choice will be. Also, new options you have not yet considered may present themselves while you look at the scenario as a whole. Always seek out a friend or family member who you find wise and knowledgeable if you cannot come to a conclusion on your own. This person will help you make sense of your thoughts and offer a new perspective. Make sure to do what you think is right and do not allow others to make choices for you that affect your life. Ethical decisions are generally the most difficult choices you will have to make because not everyone will see your choice as the correct resolution to your problem. (2309)

**REFERENCES**


**ADDITIONAL SOURCES**


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