

Determining the Rules: Applying Ethics in a Tissue Engineering Course

J. Gary Bledsoe
Department of Biomedical Engineering
Saint Louis University, St Louis, MO

As a part of a course in Tissue Engineering (TE), a three-lecture series of ethical discussions has been implemented. The three lectures are meant to give the course participants a brief background in ethical theory and practice, to discuss current ethical issues in medicine and medical research, and to implement a set of “ground rules” that the class must observe while designing a tissue engineering solution to a clinical problem as part of their course project. Four ethical bases are discussed including Deontology, Consequentialism, Natural Law, and Theology, but these are covered briefly in class because all the students in the TE have completed a course in ethics as required by Saint Louis University. Next, the course becomes very discussion oriented and covers several current topics in biomedical ethics. The topics are suggested by the participants and have included xenopplants, fetal tissue usage, stem cell research, cloning, corporate profit taking in medicine, animal rights, and healthcare access. Following the open discussion, “ground rules” are established.

Ethical Theory and Foundations

There exist a number of ethical theories upon which one could build a foundation of ethics. However, for this series of lectures, four theories have been chosen because they represent commonalities from the large number of course sections offered at Saint Louis University. Thus, the TE course can deal with the theory briefly, drawing on the common background of the course participants.

The first of the ethical theories discussed is deontology. Presented by Immanuel Kant (1724-1804) in several works, deontology is the moral theory that claims that some acts are morally obligatory regardless of their outcome on the happiness of those affected. With the literal meaning “duty theory”, deontology refers to a common set of moral prescriptions that can be recognized as duties¹. For example, “One ought not lie or defraud others”; “One should help those in need but not make them dependent”; “One must develop one’s talents.” According to Kant these rules are reducible to one supreme principle called the “categorical imperative” and can be stated as “Treat all humans as ends in themselves having their own concerns and choices, and never merely as means to be manipulated for your own ends.”²

Consequentialism and the sub-system, utilitarianism, look to the consequences or utility of the action on those affected by the action. In short, an act is morally right if and only if it maximizes the happiness of everyone affected with respect to all alternative acts. In mathematical terms, the principle of utility is as follows: from a set of P policies, choose the

policy, p_i , whose enforcement will maximize the sum of the utilities of each relevant member of the community³. If one refers to the sum of the utilities as the total utility, $TU(p_i)$, then

$$TU(p_i) = u_1 + u_2 + \dots + u_n$$

Or

$$TU(p_i) = \sum u_j, \text{ where } j=1,2,3,\dots,n.$$

Utilitarianism defines happiness as intended pleasure or absence of pain where pleasure is more than just the pleasure of sensation; it is the pleasure of intellect, of feelings and imagination, and of moral sentiment.

Natural Law is the precept that one should “do good and avoid evil,” and many authors have contributed to the abundance of works on Natural Law. Saint Thomas Aquinas uniquely presented the idea of natural law theory as 1) a theory of human nature and endowments, 2) the idea of intrinsic good, 3) the primacy of conscience, 4) the constituents of a moral act, and 5) the double effect. To Aquinas, nature is the kind of being one is; human nature is empirically observable, and a human being exists even if it does not actualize its endowments. He recognizes intrinsic good and assumes that intrinsic good is an existential value. The “courtroom” of moral action is conscience, and moral action includes not only the act but also the end and the circumstances. It is the individual’s responsibility to be properly informed in order to make a sound moral judgment. Finally, Aquinas infers that one “cannot commit an intrinsic evil to bring about a good end.”⁴ Contemporary formulations have come from Martin Luther King, Gandhi, and others. One notable statement connecting human rights to natural law comes from Herbert Marcuse, “If we appeal to humanity’s right to peace, to humanity’s right to abolish exploitation and oppression, we are not talking about special group interests, but rather interests demonstrable as universal rights.”⁵

Theology as an ethical theory is broad and far beyond either the scope of the course or of this writing, but it is important to note that modern theologies have an inherent moral code some of which can be related to previously discussed ethical theories. Christians look to the Bible for appropriate human responses, and many theologians believe that the Bible sets forth a collection of natural laws. To Christians, the laws of nature and science are of the same source as Biblical law and should be viewed as complementary sets of laws if not the same set⁶. The Jewish tradition requires man to exhibit Godlike behavior. In short, what God hates, men must hate (Deut. 12:31). Muslims follow specific instructions drawn from the Quran and from the conduct of Prophet Muhammad and set forth as Sharia or Islamic Law. Islamic Law is open for interpretation by Muslim judges, and this open interpretation has led to a broad range of applications of the Law. However, a central focus of Islam is that both law and ethics are ultimately concerned with the moral obligations of society toward God⁷.

Particular ethical codes that are applicable to biomedical ethics include the healthcare principles of non-maleficence/beneficence, autonomy, justice, universalizability, and rationality, as well as the Nuremberg Code that was established following World War II. Both modern healthcare principles and the Nuremberg Code establish that a procedure should cause no harm and offer beneficial outcome and that the patient be informed and autonomous. Adherence to applicable standards is assured by the Institutional Review Board at an institution performing

research on human subjects and was established as a requirement by the Public Health Service (PHS) for any institution receiving PHS funding.⁸

Current Ethical Issues in Biomedical Research

Current issues in biomedical research were discussed in an open class forum, initiated with a discussion of xenoplasms, transplanted animal tissue. Some issues concerning xenoplasms are the potential introduction of animal pathogens to humans, greater supply of donor tissues from animals than from humans, lack of success of early trials, animal rights, and the reality of patient benefits. Regarding the introduction of pathogens, the course participants generally believed that pathogens are easily controlled, particularly in the breeding colonies of animals used for such purposes. They pointed out that porcine heart valves are not derived from slaughtered pigs, but from animals that are specifically bred for the purpose of providing donor tissue. The participants also indicated that there are a variety of tests available to determine the presence of pathogens and that pathogenic tissue would not be used for transplantation. The participants agreed that there was potentially a greater supply of donor tissue from animals than from humans. Humans are many times reluctant to allow donation of tissues from their recently deceased loved ones; animals have no choice. Class participants also pointed out that it is considered ethically acceptable to consume animals for food, so why should consumption of tissues for transplants be any different. They also felt that the lack of success of early trials using xenoplasm tissues could be overcome, and that the lack of success should not be a deterrent to further investigation. One student explained that she believed that God gave man dominion over animals, and therefore animal rights should not be an issue. The group indicated that there was reason for concern about the benefits to patients receiving xenoplasm tissues. These patients receive a cocktail of drugs designed to prevent rejection and infection, but both rejection and infection remain problems to be overcome. The question to be answered is, 'is the outcome worth the risk'? Many of the participants believed that the outcome was not worth the risk at the present time.

A second issue was use of fetal tissue and stem cells. Interestingly, the issues of fetal tissue and stem cells were on the minds of those in the course because of the debate over government policy and the stand taken by President George W. Bush to prohibit the use of federal funds for stem cell research. The issues taken up by the class corresponded with public debate over the sources of fetal tissues and the treatment of embryos from which stem cells are taken. First was a concern that widespread use of fetal tissues would lead to an increase in the number of elective abortions, and that women would attempt to seek compensation for fetal tissue. A lesser concern was that women might conceive for the sole purpose of creating a transplant donor, and that medical therapy might become dependent on tissue from elective abortions. That elective abortion might become more legitimized if fetal tissue research becomes widely accepted was a non-issue with the class. They felt that the public is already polarized over elective abortion, and the polarization was not likely to change as a result of fetal tissue usage.

Other issues discussed included cloning, corporate profit taking in medicine, and healthcare access. On cloning, the class saw little benefit from cloning research; however, their opinions seemed to be based on the idea that cloning would lead to the attempt to create a

“master race” or an “undefeatable army”. When it was pointed out that cloning might lead to an infinite source of donor organs, the class was concerned about what might happen to the clones. Would the clone be allowed to grow to maturity and the organ harvested? In the end, the entire class was against the idea of cloning. On corporate profit taking in medicine, the class seemed to accept that in a capitalist society, corporations must be allowed to profit, but they were concerned that many corporations profit extensively at the expense of those who cannot afford expensive technology. One student pointed out that most corporations invest in products that never make a profit, so they must be allowed to profit where they can to cover areas that are not profitable. Access to healthcare was a concern, but a sub-issue of availability of prescription drugs became the topic of discussion.

The Rules

The end result of the series of lectures on ethics was the establishment of a set of rules that the class was to observe during completion of their TE design project. Individual rules were suggested by the participants and accepted by majority vote of the class. The established rules were:

- 1) Projects must adhere to accepted Healthcare principles that include non-maleficence/beneficence, autonomy, justice, universalizability, and rationality, as well as the Nuremberg Code.
- 2) Xenoplant tissues/cells were acceptable for use.
- 3) Fetal tissues derived from normal births were acceptable for use. These tissues include placental tissue, umbilical cord, and cells derived from each.
- 4) Fetal tissues derived from electively aborted fetuses were not acceptable for use.
- 5) Human embryonic stem cells were not acceptable for use; however, human stem cells derived from other sources (bone marrow, umbilical cord, etc.) were acceptable.

Conclusions

Biomedical Engineering students at Saint Louis University are very capable of understanding and applying an ethical code in their course projects and during their careers. Because they are required to take a course in ethics prior to taking TE, they have a basis for understanding applicable ethical principles in tissue engineering. They do not allow technology to cloud their personal convictions. However, they understand that technology is important and must be used with caution to prevent the compromise of their ethical standards.

References

1. Charron, W., *Deontological (Kantian) Moral Theory*, E.A.t.C. Seminar, 2000: St Louis.
2. Guyer, P., ed. *Kant's groundwork fo the metaphysics of morals: critical essays*. 1998, Rowman and Littlefield: Lanham, MD. 369.

3. Charron, W., *Consequentialist Moral Theory: Utilitarianism*, E.A.t. Curriculum, 2001: St Louis.
4. Kavanaugh, J., *Natural Law: A selective summary-review with emphasis upon contributions from Thomas Aquinas and contemporary formulations*, E.a.t. curriculum, 2000: St Louis.
5. Marcuse, H., *Five Lectures*. 1968, Boston: Beacon Press.
6. Shelton, C., *Morality of the heart: a psychology for the christian moral life*. 1990, New York: Crossroad.
7. Nanji, A., *Islamic Ethics*, in *A Companion to Ethics*, P. Singer, Editor. 1993, Blackwell Press: New York.
8. King, T. and C. Patrick, *Ethical Consideration of Tissue Engineering on Society*, in *Frontiers in tissue engineering*, C. Patrick, A. Mikos, and L. McIntire, Editors. 1998, Pergamon: New York. p. 311-340.

J. GARY BLEDSOE

J. Gary Bledsoe is an Assistant Professor of Biomedical Engineering. Dr. Bledsoe received his BS from The University of Tennessee, Martin, in Engineering Technology, MS from the University of Memphis in Biomedical Engineering and PhD from the University of Memphis in Engineering. He teaches Biomaterials, Biomechanics, Tissue Engineering and Interfacial Phenomena. Research interests include biomaterials and interfacial mechanics.