Ethical Aspects in Bioengineering Research

LILIANA ROGOZEA,
GABRIELA SECHEL
ANDREEA FLEANCU
Fundamental and Prophylactic Medicine Department
Transilvania University of Brasov
Eroilor 29, Brasov, ROMANIA
r_liliana@unitbv.ro    http://www.unitbv.ro

Abstract: This paper presents the ethical standards for carrying out bioengineering research in correlation with human subjects and according to the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. Knowing and developing the ethical standards in this field is connected with the assurance of the dignity, rights, safety, and well-being and with the scientific progress. Developing the research in bioengineering must be predominantly motivated by the concern for the community benefit, for all people without any discrimination of age, gender, economic status, cultural or ethnic considerations.

Key Words: ethics, bioengineering, standards, dilemmas, rights

1. Introduction

The consideration of the ethical issues relating to bioengineering research is a recent phenomenon, connected with the expansion of the engineering action to human life, because bioengineering is really a multidisciplinary approach aimed at solving the problems in biology and medicine. [9, 10]

Developing like a branch of engineering interweaved with the medical field, bioengineering needs specific standards and the application of scientific and mathematical principles to practical ends such as the design, manufacture, and operation of efficient and economical structures, machines, processes, and systems.

![Fig. 1: A few areas where bioengineering has developed are shown in fig.1.](image)

Bioengineering, as the application of engineering methods and knowledge to biology and medicine, constitutes a decisive extension of engineering beyond its previous restriction to the non-human and even non-living world. The classical fields of civil, mechanical, electrical, and electronic engineering are all focused on making (to adapt a standard definition) "the properties of matter and resources of energy in nature available to human use." [7]

2. Historical aspects

From Hippocrates, Plato to Avicenna and Maimonides, going on with Descartes, Darwin, Porter, biomedical ethics has given rise to many contradictory discussions, and in the last century, ethics in bio-engineering is another topic more and more tackled with.

Machiavelli, the author of The Prince, is well-known for his belief that politics and business are usually unethical, but Thomas Hobbes claimed that “Human nature leads men to lead solidarity, poor, nasty, brutish and shorts lives”.[1].

Utilitarianism, Kantianism or virtue theory had been developing in the meantime and developed a set of rules in accordance with the different position about the respect of autonomy, beneficence, non-malfeasance or justice.

In this context, developing the science and technologies gives a direct connection between bioengineering and health, as it is mentioned by J.A. Flexman and L. Lazareck: “Biomedical engineering impacts health care and contributes to fundamental knowledge in medicine and biology. Policy, such as through regulation and research funding, has the potential to dramatically affect biomedical engineering research and commercialization. New developments, in turn, may affect society in new ways. The intersection of biomedical engineering and
society, and related policy issues must be discussed among scientists and engineers, policy-makers and the public. As a student, there are many ways to become engaged in the issues surrounding science and technology policy.

Magna Charta Libertatum, Habeas Corpus Act, Bills of Rights to the Declaration of Helsinki and Documents of the European Council was focused in standardizing the ethical attitude, developing a moral scientific attitude and reducing the risks of abuses in different fields of bioengineering.

Ethics was seen, usually, like a sub-division of philosophy. But we think that the ethics have more and more practical approaches and a lot of sub-division were described.

As Thompson I., Melia K., Boyd K said: “Ethics, as Aristotle observed over 2000 years ago, is a practical science. It is practical in two senses: first, it must be rooted in actual practice, and second, it must help us to make more soundly based decisions so as to deal effectively with real problems in life” [14]

2. Ethical Fields in Bioengineering.

The main field of application for bioengineering are: mechanical engineering, chemical engineering, integrative biology, molecular and cell biology and material science and engineering, computer science, math and statistics, electrical engineering, integrative biology, and nuclear engineering. [5]

The principal fields of bioengineering and their expertise area are present in the next figures.

Artificial heart raises a lot of dilemmas for medical ethics experts but also for theologians, social scientists and the general public.

Skin grafting raises dilemmas according with: donor selection, surgical procedure, risks and of course about facial identity, reconstruction.

Another section of bioengineering must be connected with bioinformatics and genomics, computational bioengineering and its branches: genetic engineering, mapping or analysis, which must be used for: genetic testing, gene therapy, cloning, human genome project or disease prediction. (fig.3)

According to James Watson and Francis Crick the discovery of DNA evolution to gene therapy or gene testing is only a matter of time.

We change a lot of opportunity for humanities by developing speedy cars, airplanes or computers but the mirage and the impact of genes and therapies using this concept are still high. [8]

Prevention using human genome project, cloning or disease prediction is a combination between old and new vision and an opportunity for reducing the disease in community.
Macromachines and robotics are connected with implantable or sensory devices and limb replacement and put some ethical problems according with: biomedical microelectromechanical systems, monitoring devices, insulin diction devices or robotic replacement arms. [2](fig. 4)

Using devices in medicine involves a lot of ethical challenges not only during the educational period (learning only about the few companies which make devices) but also during the treatment when they are frequently used for seriously ill persons.

Robotic replacement arms are useful devices but they constitute also a possibility to improve the chance of recovering and returning to normal activities.

According with society development, a few ethical challenges in research are similar in medicine and engineering, in compliance with human rights.

A parallel track of ethical reviews for the proposed research studies should be considered. Under such an approach, the professional community from doctors, engineering and bio-engineering must set up their ethical rules and the development of a frame should be carried out by the research institution.

In fact, engineers, doctors or bioengineers are in contact with ethics problems not only during their studies or works in hospitals, consulting rooms or factories but also during their participation to government-funded research or when they submit articles for publication in journals. [11]

Thinking about ethics or morals rules could help us to distinguish between right and wrong, acceptable and unacceptable behaviour, in order to develop a modality of approaching our attitude according with a popular rule, well known by the century "Do unto others as you would have them do unto you".

3. Ethical research – a border approach in bio-engineering

The foundations of medical ethics go back to writings attributed to Hippocrates and another oath, and deal primarily with the relationship between individual physicians and their individual patients.

The concept of ethics had not modified until the 18th century, and for a long time the ethics in medicine and engineering had been seen like two different ways of approach the same rules.

The research ethics is strongly connected to observing rules previously stated by Charles Darwin:..."My success as a scientist, no matter how great, was determined by spiritual qualities and complex and varied conditions. Among these, the most important were the love for science, unmeasured patience to reflect upon a certain subject, diligence in observing and gathering facts as well as inventiveness and common sense... [13]

Any researcher in the field of life sciences should be updated with the main regulations in the field: Declaration of Tokio (1975), of Manila (1981) or of Hawai (1983). [20, 21]

Biochemistry, biophysics, material sciences, mechanics are more and more involved in developing medicine. New medicines and new technologies have been developed and have contributed to the increase of life expectancy. The advances in medicine are related to new nano-materials, to micro or nano-devices, to nanotechnologies and the nano-bio-IT joint research which represents the path already encouraged by different groups or with Biomedical Imaging Signal Processing (Tomography, X-ray, cellular imaging, ultrasound devices, digital radiography, biomedical image analysis, mammography or Nuclear Magnetic Resonance Imaging. (fig. 5)

Scientific research is more and more often subject to it, although the specific requirements and the number of research programmes, which have an ethics committee, are relatively reduced, even in sensitive domains. The researches in fields linked with bioengineering should give the possibility to manipulate the genetic material, to discover or to prevent the diseases. [3]

It is well-recognized that “Ethical research can be compared to a medal with two sides: one side refers to ethics theory, which means to thousands of years of philosophy (Mac Intyre, 1976), the other one, refers to empirical psychology. Both sides can be conjoined in one of our research question that is if theoretical ethical positions of practical philosophy can be found empirically.” [15]

The principal ethical problems which must be taken into account are: conflict of interests and consent. According with the conflict of interests and the inadequate conduct Beauchamp underlines "when the
personal interest or an obligation of a researcher’s role comes into conflict with an obligation to sustain the interest of another party, compromising the natural expectations with regard to reasonable objectivity and to impartiality related to the other party” [12]

Consent could be tacit, implicit or implied, supposed or informed based on competency, volunteering (preliminary conditions), revealing information (nature and character of treatment proposed), anticipating results, and acknowledging possible major risks. More and more people use now the informed consent is “a consent based on autonomy, authorizing in an individual way a medical intervention or involvement in a particular research” being the one that must be legally obtained in institutions, as social rule…” [16, 17]

4. Romania – specific ethics aspects

In order to prevent ethical abuses connected with scientific progress in many countries (Romania not included) there were founded research and information institutes in the field of bioethics like Milazzo group, or GRMCQ group.

Romania does not have a national independent committee of bioethics that should stand for the guarantor for the observance of the science sacrament and human research.

One of the most important ethical regulations are the law No. 206 of May 27, 2004 regarding the good conduct in scientific research, technological development and innovation where it is showed that: “The moral principles and procedures designated to observe them are those stipulated in the Code of ethics and professional deontology of the research-development staff, elaborated by the national authority for research-development”. [18]

One of the greatest dangers is to use Romania as a basis to fulfill experiments with high degree of ethical risk. In order to avoid these ethical rigors, there must be observed the rules assumed on the European level.

Developing an ethical manner of life must be a preoccupation of the authorities, universities or politicians based on the customs and the level of culture and education. Two Romanian researchers think that: “The most important thing in understanding a culture is to obtain a comparative and critical perspective. The fact that we have been talking about that organization’s culture, usually for such a short time, is due to the lack of visibility of the culture. When it becomes visible, we are sure we can change it instantly”. [4]

Also, main changes will occur in the teaching methodology. “The vertiginous technological advance of our society entails continuous learning and this is generating the necessity of using educational models that allow the students to learn to learn”. [6]

8. Conclusion

From the ethical point of view, the interdisciplinary research is more and more often anchored in regulation, inter-connected between various activities of research.

Bioengineering must be placed at the interface between doctors or engineers, and the research requires more regulations.

In a dynamic society the bioethics in bioengineering must be dynamic respecting human right.

In a report of National Bioethics Advisory Commission, SUA, 2001, having the subtitle: „Education as the key to promoting local responsibility” this issue is perfectly underlined: „It is unrealistic to think that ethical obligations can be fully met without guidance and resources. To help researchers and IRBs fulfill their responsibilities, the federal government should promote the development of education, certification, and accreditation systems that apply to all researchers, IRBs members and staff, and all institutions. [19]

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