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Teaching Ethical Issues in Biomedical Engineering*

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In many places throughout the world, Biomedical Engineering (BME) still awaits formal recognition as a profession. Its intrinsically multi and interdisciplinary characteristics partly account for that delay. This is aggravated by the lack of precise ethical rules that delineate and delimit the professional responsibility of biomedical engineers. In this paper, some of the ethical issues that are of interest to biomedical engineers and how they can be integrated in biomedical engineering education are discussed. A program outline for bioethics, which includes the topics that should be addressed in engineering schools, is presented.

INTRODUCTION

IN MANY PLACES throughout the world, Biomedical Engineering (BME) still awaits formal recognition as a profession. Its intrinsically multi and interdisciplinary characteristics partly account for that delay. This is aggravated by the lack of precise ethical rules that delineate and delimit the professional responsibility of biomedical engineers.

Thoughtful attention must be paid to the factors that actively contribute to the lack of recognition of BME as a profession. Some of this may be due to the confusion that is created through the overlap of professional roles between biomedical engineers and other health care personnel. Professional ethics is one of the areas in which this overlap occurs. Medical ethic postulates are frequently considered by extension to encompass biomedical engineering ethics, although the moral obligations of medicine and BME differ due to the nature of both activities [1]. On the other hand, these two disciplines share a number of professional issues, and the consequences of their actions are common since they both may affect human life.

Over the last decades, scientific and technological developments in medicine and engineering have contributed to coining the term 'bioethics'. This 'ethics of life' is everybody's responsibility and not just a matter of a specific professional morality [2]. Thus, teaching ethics in biomedical engineering must now conform to the broader scope of 'bioethics', a concept that implies a community concern.

Traditionally, engineering education has been oriented towards inert material, a material lacking usual or anticipated action from a chemical or biological point of view. Problems arise when engineers deal with living material either directly or indirectly. Classical tools were 'designed' to work on substances that do not show a pre-established order as the living organism does. Technology can alter the essence of a living organism—a working unit—when affecting its components; these are arranged according to a predetermined scheme in preparation for a particular function. It is difficult then to clearly identify the set of moral principles that govern biomedical engineers, moreover, if these principles only conform to the standards of traditional engineering. Thus, three questions arise for BME Ethics educators: what to teach, when to teach, and how to teach. The following sections are intended to address these questions.

ETHICAL ISSUES

Bioethics integrates social as well as ethical and legal issues. It must be noted, however, that bioethics is strongly biased to medical issues [3]. Due to its political and social implications, biotechnology, an area that is closely linked to BME, plays a leading role in defining moral standards of professional activity. However, biotechnology represents only a partial view of BME.

It is imperative that biomedical engineers think of all possible consequences of their profession. Whether a basic researcher or a clinical engineer, the biomedical engineer must be able to answer for his or her conduct, i.e. they must be responsible for their professional behaviour before the community and within the provisions of the law. In general, legal responsibility for the use of procedures, techniques, and devices remains a medical issue even though the basic research and design that led to those procedures was performed by engineers who followed professional guidelines.

Any course in bioethics should include the basic methodology to distinguish what is right

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We, the members of the IEEE, in recognition of the importance of our technologies in affecting the quality of life throughout the world, and in accepting a personal obligation to our profession, its members and the communities we serve, do hereby commit ourselves to the highest ethical and professional conduct and agree:

to accept responsibility in making engineering decisions consistent with the safety, health and welfare of the public, and to disclose promptly factors that might endanger the public or the environment;

to avoid real or perceived conflicts of interest whenever possible, and to disclose them to affected parties when they do exist;

to be honest and realistic in stating claims or estimates based on available data;

to reject bribery in all its forms;

to improve the understanding of technology, its appropriate application, and potential consequences;

to maintain and improve our technical competence and to undertake technological tasks for others only if qualified by training or experience, or after full disclosure of pertinent limitations;

to seek, accept, and offer honest criticism of technical work, to acknowledge and correct errors, and to credit properly the contributions of others;

to treat fairly all persons regardless of such factors as race, religion, gender, disability, age, or national origin;

to avoid injuring others, their property, reputation, or employment by false or malicious action;

to assist colleagues and co-workers in their professional development and to support them in following this code of ethics.

Approved by the IEEE Board of Directors, August 1990

Fig. 1. The Institute of Electrical and Electronics Engineers Code of Ethics.

from what is wrong and the principles of moral philosophy used to qualify an action as good or bad. This normative ethics leads to the codes of ethics that synthesise the responsibilities of each profession. Numerous professional organisations have elaborated their codes of ethics [4]. Figure 1 shows the Institute of Electrical and Electronics Engineers (IEEE) Code of Ethics. The Hippocratic Oath, perhaps authored by the Greek physician Hippocrates (4th century BC), has been adopted by the World Medical Association as the central point of medical ethics [5]. As amended in 1994, its text appears in Fig. 2. The Engineering in Medicine and Biology Society of the IEEE is currently preparing an international code of ethics for biomedical engineers. Teaching clear and practical concepts of biomedical engineering moral obligation will help engineers to focus on the moral dimension of their activities.

Due to cost and complexity, many of the new advances in health care technology must be considered scarce. The ethical allocation of these scarce resources is one of the most difficult problems facing health care workers, including biomedical engineers [6–8]. The traditional sense of health care is changing, and so is bioethics [9]. What in the past was a medical issue has turned into an interdisciplinary team decision involving biomedical engineers. In some organisations biomedical engineers actively participate in allocating new technologies. Technology assessment, i.e. identification and evaluation of the implications of technology used to improve health and life quality, represents a direct link between

At the time of being admitted as a member of the medical profession:

I solemnly pledge myself to consecrate my life to the service of humanity;

I will give to my teachers the respect and gratitude which is their due;

I will practice my profession with conscience and dignity;

The health of my patient will be my first consideration;

I will respect the secrets which are confided in me, even after the patient has died;

I will maintain by all the means in my power; the honor and the noble traditions of the medical profession;

My colleagues will be my sisters and brothers;

I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient;

I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;

I make these promises solemnly, freely and upon my honor.

Fig. 2. The Hippocratic Oath, adopted by the 2nd General Assembly of the World Medical Association (Geneva, 1948) and amended by the 46th WMA General Assembly (Stockholm, 1994).

biomedical engineers and policy makers. It allows engineers to demonstrate the contributions of health care technology [10], but they must also now confront more responsibility for cost-effective designs and complete testing and review during the development of medical devices [11]. Needless to say, the bioethical issue of resource allocation has global implications.

Bioethics addresses the general standards for respecting human dignity and for protecting individuals within the context of the clinical applications of biomedical research and development. There are some fundamental values that must be understood:

- human dignity and integrity,
- freedom and responsibility,
- solidarity and social justice [12],

as well as concepts of risk, consent, autonomy, and privacy.

There are some fields in bioethics that are more directly related to medical research, e.g.

- medically assisted procreation;
- the human genome project;
- brain research;
- end of life issues;
- transplantations;
- patient's consent;
- truth telling;
- research methodologies.

Other fields, however, have a social impact. Biomedical engineers cannot ignore these fields. They must understand and answer public attitudes regarding the perception of ethical issues, especially with regard to fundamental values. For example, automatic data transfer by computerised information systems affects confidentiality and privacy in medical data and requires responsible data management. Health care budgets create a social dimension for the choices to be made in resource allocations. As already mentioned, biomedical engineers are generally involved in preparing budgets and determining priorities in health care [13]. Bioethical issues for biomedical engineers also include the use of human and animal subjects for experimentation and misconduct in science.

Bioethics education cannot concentrate only on issues specific to a particular profession. The wide scope of bioethics points to the study of ethical issues that might be compatible with a given professional practice but unacceptable for an interdisciplinary group. The occasion and conditions for using medical technology may be contradictory for physicians and engineers. The legal use of medical devices in their prototype phase, although oriented toward urgently solving the health problem of a patient—the primary consideration of physicians—may conflict with engineers seeking appropriate application of technology and knowing its potential consequences. In emergency situations, the use in adults of paediatric instruments—or life supporting devices in general—whose technological limitations may be well known to engineers, could give rise to ethical conflict with physicians seeking the immediate recovery of their patients. Education in bioethics should thus emphasise the comparison of ethical issues familiar to those working in certain professions (medicine, nursing) with parallel ethical issues arising in other professions like engineering [14].

ETHICS IN THE BME CURRICULUM

The first purpose of teaching ethics in engineering schools is to make students understand that ethical issues are integral to engineering. Students must be able to recognise ethical problems, and they must develop the necessary skills to deal with those problems. Also, by understanding a code of ethics and by agreeing to act according to it, students will build a strong identity as professionals [15].

Several years ago, the Accreditation Board for Engineering and Technology (ABET) in the United States recommended that all engineering programs should address ethical issues. It has been argued that ethics should be taught by engineering professors as a way of showing students that ethics is central to engineering and not peripheral to it, as students might assume if all ethical issues were taught by philosophy faculty [16]. Either approach is insufficient for an integrated ethics education. Studies have shown that beginning students who took fundamental ethics courses that were taught by ethicists scored higher on Rest's Defining Issues Test (DIT), a test designed to assess the development of moral judgement, when they took the test later in their educational program [17, 18].

Ethics education for biomedical engineers should cover both the study of the fundamental values of bioethics and those topics that are related more specifically to the biomedical engineering profession. Therefore, it is recommended that students be introduced, as early as possible, to ethics values from a philosophical point of view. Hopefully, this knowledge would prevent even highly motivated student from developing rather narrow ideas about how good or bad a professional action is [19].

Of primary importance in traditional engineering education is the issue of safety, a concept strongly tied to engineering culture and one that is transmitted to students at the beginning of their career and in every course they take [15, 20]. Experienced engineering faculty are role models for students at least until graduation. In professional life, engineers must follow the professional standards of their employers. This may eventually give rise to ethical dilemmas if those standards are oriented mainly to production.

Addressing professional issues for BME students at engineering schools is not a straightforward process. BME is conceptually dynamic and its scope widens frequently to incorporate new disciplines and specialities. This pushes biomedical engineers on a continuous search for a professional identity, as shown by the numerous published definitions of the activity. Also, students are not fully aware of the potential for their professional knowledge to affect health and human life. The biological system, in fact the 'final user' of the BME student's work, is distant, complicating the identification of the ethical issues that accompany engineering research and development of procedures and devices.

Strong qualifications are required of BME faculty if they are going to act as models for their students and help them narrow the gap between academia and practice, i.e. between instruction and real-world applications. For BME students heading either to research and development or to the health care system, faculty experience is key to learning. Teachers must help students to develop the skills they need to think critically about ethical issues.

Medical students also experience some distance between the ethics of classrooms and the ethics of hospitals. Since they face ethical dilemmas when they are in contact with patients, the best time to teach ethics to medical students is during the residency years when integration of academician and practitioner is possible [21, 22].

No biomedical engineer can ignore the biological world or the patient, even if he or she is not directly working in the health care field. Ethical issues closer to medicine than to engineering should also be addressed by BME students, particularly by those who will not face ethical dilemmas associated with close contact with patients, e.g. in clinical engineering. There is no equivalence to the residency period in hospitals for all the specialities of biomedical engineering. Thus, for instructional purposes, medical ethicists and clinicians must be part of the faculty for teaching bioethics to BME students. Bioengineers need to gain a better understanding of medical education and medical practice. Medical ethics is fundamental to this [23].

Professional issues are usually summarised in the obligations of moral conduct represented by the codes of ethics, although it is worth mentioning that not every code of behaviour claims to have ethical justification. On the other hand, some codes support the right of the professional to refuse work that compromises the professional's personal ethical values, even if the act in question is not morally objectionable by the profession as a whole [24].

If one accepts that a code is the first word in identifying ethical problems for the practising professional [20], then discussing the statements of ethical codes is an appropriate classroom exercise for instructors and students (see Figs 1 and 2). This group discussion methodology is essential in biomedical engineering ethics education. It raises the student's self-confidence in ethical values by making public each individual's moral questions and concerns and by allowing individuals to learn that their concerns are generally shared by their instructor and classmates [15]. Another widely used approach to understand ethical reasoning involves case studies, either real or fictional. Through these examples, students can identify the morality underlying professional attitudes [19].

Of relevance for biomedical engineers is the study of the Björk–Shiley heart valve failure case. The BSCC (Björk–Shiley Convexo–Concave) mechanical prosthetic heart valve is famous for a history of failure, after its introduction in 1976 to become the most popular prosthetic valve for over a decade. During clinical trials, the valve showed a material fatigue leading to weld fractures. While the manufacturer modified welding and quality control procedures, the valves were not withdrawn from the market, nor were patients notified of eventual failures. Additionally, the FDA—as regulatory agency—was ineffective at ensuring public health as shown by a delay in recommending valve removal from the market, lack of investigation of the manufacturer and failure to enforce patient notification [25, 26]. For students, this case study would be highly illustrative and a good example of ethical violations involving several parties.

Classroom work in ethics will certainly follow the general procedure used elsewhere in engineering schools, i.e. problem solving. The decision-making process is not foreign to ethics since the first step in this process is problem identification, a main issue in ethics and one that is sometimes not clearly achieved. Once the problem is known, the student must be aware that it has a solution. Students must solve this moral problem and not be surprised when they find that the essence of some solving strategies is common to other disciplines like physics or math [15, 19, 20].

ETHICS PROGRAM OUTLINE

It is difficult to find ethics courses that address every ethical issue of interest for BME students [14, 16, 27–29]. This section lists the topics that should be covered by an ethics education program for biomedical engineers. The list is not intended to represent a course syllabus but rather a program outline describing the topics that are to be addressed in biomedical engineering education. References [30–37] represent valuable textbooks.

1. BIOETHICS FUNDAMENTALS

1.1 Metaethics. Ethics as a discipline. Study of the basic concepts of right and wrong, good and bad.

1.2 Descriptive Ethics. Analysis of morality within different cultures.

1.3 Normative Ethics. The morality of an action. Nature, motives or consequences of an action. Divine command. Value theory. Utilitarianism.

2. RESEARCH ETHICS

Human subjects and animals for experimentation. Control of science and technology.

Conflicts of interests in research. Scientific misconduct. Ethics committees. Data management.
3. PROFESSIONAL ETHICS
3.1 Engineering ethics. Public health and public safety. Conflicts of interests. Ethical issues in design and manufacture. Risk analysis. Cost-benefit analysis. Resources allocation. Negligence. Professional restrictions and professional responsibility. Rights of engineers. The ethics of engineering organisations. Codes of ethics.
3.2 Medical ethics. The patient–physician relationship. Autonomy and privacy of patients. Informed consent. Professional conduct and confidentiality. Truth telling. Biotechnologies. Reproductive techniques. Genetic engineering. Clinical trials. Resources allocation. Euthanasia. Conflicts of interests. The Hippocratic oath.
4. SOCIAL ETHICS
4.1 Social morality and personal ethics. Public policies. Ethical criteria for resources allocation. Governmental, inter and intra-institutional allocation policies. Legal ethics. Scientific advances and legal changes. Health and welfare. Environmental ethics. World population and natural resources. Rural development.

As mentioned above, this program would require highly qualified instructors with different backgrounds and experience, e.g. ethicists, research and field engineers, and research physicians and clinicians. Pedagogical methodologies may include case studies, group/panel discussions, debates, role playing, writing assignments, and seminars. Upon completion of the program, biomedical engineering students should have learned the fundamental values of ethics and achieved the necessary skills for solving moral problems.

CONCLUSIONS

The growing field of biomedical engineering requires that institutions that authorise lawful registration of engineers accept BME as an independent profession. Specialised accreditation boards for the technical assessment of professional abilities and eventual registration of biomedical engineers should be constituted everywhere. Modern health care represents the integration of medicine, management, and engineering, each with different roles and comparable hierarchies. All of these require an understanding of fundamental moral values and the existence of a BME professional code of ethics.

As for any other calling, the conduct, aims, and qualities that characterise biomedical engineering must be openly and precisely declared to the community. Bioethics is a social concern, and teaching and learning ethics should be a daily commitment for biomedical engineers and a way of strengthening biomedical engineering as a profession.

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