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Biomedical Engineering Ethics

Biomedical engineering is the application of engineering principles and techniques to medicine. It combines expertise in engineering with expertise in medicine and human biology to develop technologies and techniques for healthcare and patient care. Biomedical engineering emerged as a field after World War II, and has expanded ever since. As a field, it is very broad, with applications ranging from molecular imaging to the construction of artificial hearts. Biomedical engineering is however narrower in scope than *bioengineering*, or *biological engineering*, with which it is sometimes equivocated. Bioengineering focuses on the engineering of biological processes and systems in general, and includes not only biomedical engineering but also agricultural engineering, food engineering and biotechnology.

In part because biomedical engineering it itself a new field, there is currently no distinct academic field of biomedical engineering ethics. Ethical issues in biomedical engineering are currently studied in the fields of bioethics, medical ethics and engineering ethics. Yet, professional ethical issues in biomedical engineering are often different from the ones traditionally discussed in these fields. Biomedical engineers differ from medical practitioners, and are similar to other engineers, in that they are involved in research for and development of new technology, and do not engage in the study, diagnosis and treatment of patients. Biomedical engineers differ from other engineers, and are similar to medical practitioners, in that they aim to contribute to good patient care and healthcare. The ethical responsibilities of biomedical engineers thus combine those of engineers and medical professionals, including a responsibility to adhere to general ethical standards in research and development of technology and to do R&D that adheres to the specific standards set forth by medical ethics and bioethics. Although biomedical engineers are not medical practitioners, one could say that they are indirect practitioners, since the technologies and techniques they develop co-determine medical practice.

General Ethical Issues

In biomedical engineering, a distinction can be made between ethical issues in the R&D practice itself and ethical issues regarding the implications of developed techniques and devices for medical practice. Within R&D there are ethical issues regarding human and animal experimentation and the use of biomaterials, as well as general issues of R&D ethics like truthfulness and the avoidance of conflicts of interests. Next to such issues inherent to their own practice, biomedical engineers have a responsibility to anticipate on the consequences of their designs for medical practice and to ensure that technologies and techniques are designed in a manner consistent with and supportive of ethical principles for medical practice. Such principles include beneficence (benefiting patients), nonmaleficence (doing not harm), patient autonomy (the right to choose or refuse treatment), justice (the equitable allocation of scarce health resources), dignity (dignified treatment of patients), confidentiality (of medical information) and informed consent (consent to treatment based on a proper understanding of the facts).

Particular ethical questions arise in relation to *human enhancement*. Whereas the devices and techniques developed by biomedical engineers are usually designed to support therapy or diagnosis, they may also be designed to enhance healthy human traits beyond a normal level. This is called human enhancement, and it is morally controversial because it moves traits beyond boundaries of the human species, and therefore has the potential to create superhumans. If medicine were to engage in human enhancement, it would move beyond its traditional mission, which is merely curative and preventive. Enhancement may even require the impairment of healthy human tissue or organs to fit augmentations. It therefore remains controversial whether biomedical engineers (and medical practitioners) should engage in human enhancement.

Let us now turn to some specific fields of biomedical engineering and consider major ethical issues in them.

Cellular, Genetic and Tissue Engineering

These fields involve recent attempts to attack biomedical problems at the microscopic level. *Cellular engineering* is a field that attempts to control cell function through chemical, mechanical, electrical or genetic engineering of cells. It attempts to understand disease processes at the cellular level and to intervene by means of miniature devices that stimulate or inhibit cellular processes at target locations to prevent or treat disease. *Genetic engineering* specifically aims to control the genetic material in cells. Most research goes into *somatic cell therapy*, which is the genetic modification of bodily cells other than sperm or egg cells in order to replace defective genes with functional ones. It is being clinically tested to treat inheritable diseases, cancer, diabetes, and various neurodegenerative disorders. There is now considerable agreement that somatic cell gene therapy to treat serious diseases is ethical.

Germline engineering, which is not currently used therapeutically but which is being studied, is a more controversial practice in which genes in eggs, sperm or very early embryos are modified. It is controversial because it leads to inheritable modifications of the genome that are passed on to future generations. The long-term side effects of such engineering are currently unpredictable, and there are also concerns that such engineering violates the rights of future generations or amounts to "playing God". Also controversial is genetic engineering to enhance human traits such as intelligence or strength, whether practiced on somatic cells or germline cells. Such genetic enhancement is controversial for the same reasons that apply to other types of human enhancement.

Tissue engineering is a field that aims to restore, maintain or improve the functioning of tissues or whole organs by means of biological substitutes that repair or replace these tissues or organs. One of the goals of tissue engineering is to create artificially grown organs for patients that need organ transplants. Tissue engineering strongly depends on cellular engineering as well as on biomaterials science. Major moral controversies in tissue engineering concern the use of *xenogenic* (animal or vegetative) and *human embryonic tissue* (stem and germ cells). The use of xenogenic cells and cell material is controversial because species boundaries are crossed in the process: it involves the creation and medical use of cells and tissues that, by origin, are part human, part animal or plant. The use of embryonic tissue is controversial because cells are harvested from human embryos, which are destroyed in the process, or from aborted fetuses. It has been objected that it is unethical to kill or destroy human embryos and therefore to have a medical practice that involves it, and there are worries that a demand for human embryonic tissue promotes the large-scale cultivation of human embryos specifically for this purpose.

Other ethical issues in tissue engineering concern the question whether and how specific types of tissues can be patented, the question whether human donors of cells should be able to profit from their use (which is currently not the case) and whether donors have a right to informed consent for every use of their cells (which is currently the case). The protection of privacy of donors is another issue. Tissues of donors are stored in so-called biobanks, repositories for the storage of biospecimens that are used for clinical or research purposes. Public and private organizations that own such biobanks are responsible for protecting the privacy and confidentiality of donors, but there are disagreements about the extent and manner to which this should be done. A final ethical issue concerns the question of how to balance the prolonging of life with the quality of life in tissue engineering. To what extent should lengthening the life span of humans be a goal of tissue engineering, and how should such a goal be balanced against the goal of improving the quality of life, as these goals may sometimes conflict?

Biomaterials, Prostheses and Implants

Several biomedical engineering fields have a partial focus on the development of prosthetic devices and implants. In the field of *biomaterials*, which is complementary to tissue engineering, nonbiological synthetic or natural materials are developed and used to interface with biological systems to replace, treat, augment or support tissues, organs or functions of the body. The field of biomaterials contributes substantially to the development of prostheses and implants in biomedical engineering. The development and use of prostheses and implants is a major concern of *rehabilitation engineering*, a field concerned with developing technological solutions for problems of people with disabilities and function impairments. Prostheses such as artificial hips, artificial limbs, pacemakers, speech synthesizers and retinal implants are used to restore function.

The use of prostheses and implants raises issues of human identity and dignity because it involves the addition of artificial structures and systems to human biology, or even the replacement of human tissues and organs with artificial versions. The use of prostheses and implants, particularly ones that have functioning parts, makes humans into *cyborgs*: beings that are part human, part machine. Can the resulting person still be called fully human? Can the addition of artificial part cause a transformation or even a loss of identity? Are humans still autonomous persons when they rely on electronic circuitry in their bodies? Should certain organs or functions not be replaced by artificial systems? In addition, the possibility that prostheses and implants are developed for human enhancement has also met with controversy. A more mundane issue concerns the use of biomedical devices and implants in clinical trials: what conditions must be met for the ethical and responsible testing of new biomaterial and prostheses in humans, and how thoroughly should materials and implants be tested before they go on the market?

Biomedical Imaging and Optics

Biomedical imaging is the application of engineering methods to detect and visualize biological processes. Biomedical imaging techniques are used clinically, to detect and diagnose diseases, and in basic life sciences research, to study normal anatomy and function. Biomedical imaging is usually noninvasive or minimally invasive and involves the radiation or detection of a known physical quantity, like sound, ultrasound, radiation or magnetism. Electronic data processing and analysis is then used to generate visual images.

Biomedical imaging has obvious benefits for science and healthcare. Concerns have been raised with *diagnostic imaging*, however. It has been worried that imaging for this purpose may lead to an excess of diagnoses. Diseases may be revealed that were not under investigation or for which no therapy is available, or conditions may become visible that indicate an increased probability to develop a disease. This may confront medical specialists and patients with information and (moral) choices they may not wish to have. Patients may not want to know that they have a disease for which no good therapy is available, or be confronted with a painful uncertainty whether they have or could contract a certain disease. This raises moral issues not only about the use but also the design of imaging technologies: should they be designed, for example, so that bodily conditions are made visible selectively?

Moral controversy also extends to *brain imaging*, which is reaching the point that it can reveal information about a person's mental states or plans for action. These developments raise significant privacy concerns and the frightening possibility that mind reading is used to manipulate and control people. A third and final ethical issue concerns the ethics of data manipulation in biomedical imaging. Images, whether for clinical study or for scientific analysis, are expected to be truthful and reliable, which requires that no imaging operations are performed that manipulate data and provide false information. Yet, some imaging operations, such as brightness and contrast adjustments, are clearly acceptable and sometimes necessary. This raises the question what imaging operations are permissible and to what extent imaging operations must be reported to third parties.

Neural Engineering

Neural engineering is a new field at the intersection of engineering and neuroscience that uses engineering techniques to study and manipulate the central or peripheral nervous systems. Its goals include the restoration and augmentation of human function. This is usually achieved via direct interactions between the nervous system and artificial devices. In *neuroprosthetics*, neural prostheses are developed that replace or improve neural function of an impaired nervous system. Another area of neural engineering is that of *brain-computer interfaces*, in which external computing devices are hooked up to the brain so that signals can be exchanged. Neural engineering also includes the development of *brain implants* for functional electrical stimulation of nervous tissue to restore function.

Besides involving controversial forms of animal and human subject research, neural engineering has raised ethical questions regarding the integrity and dignity of persons, as artificial neural devices may affect personal identity and make the human mind or brain partially artificial, thus turning humans into cyborgs. In addition, individual autonomy could be undermined as neural devices could be used to control cognition, mood, and behavior. This also raises questions of responsibility: can humans still be held morally responsible for their behavior when their brain has been engineered by others to function in a certain way? The possibility of *neuroenhancement* also raises significant ethical issues: should neural engineering be used to develop artifical devices that allow humans to have superior perception, cognition or motor control, or positive moods and attitudes?

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