

REPORT

BIOETHICS IN IRAN: LEGISLATION AS THE MAIN PROBLEM

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Although there are only a few centers in Iran specializing in genetic research, the numbers are increasing rapidly. All key research centers are now under the supervision of an organization called The Molecular Medicine Network. With the growing trend in genetic research, health care officials have recognized the need to draw up a detailed guideline on ethical issues. The Iranian Ministry of Health and Medical Education recently established a national ethics committee to develop some regulations in the field of bioethics. A 27-clause document was issued by the committee. However, references to genetic studies have been minimal. As such, we are trying to finalize the first draft of a guideline which encompasses the most challenging ethical implications in the field of genetics including informed consent, confidentiality, genetic counseling and potential for social harm or psychologic distress imposed by disclosure of individuals' genetic information. *Shia*, a branch of Islam and the official religion of Iran has a number of rules and concepts about some important issues of bioethics which are different to the West. In addition, Gnostic concepts integrated in Persian literature are firmly respected by the Iranian population and these lead to different interpretation of bioethical issues. In this article, the current situation of bioethics in genetics and the best way to produce simple, applicable and effective guidelines in this area are discussed.

A brief history of developing bioethical guidelines around the globe

The German Guidelines on Human Experimentation, 1931, is thought to be the first of its kind for therapeutic and scientific research on humans and remained in force until 1945. In 1947, the Nuremberg Code (1947) was issued and also contained guidelines on human experimentation. Unfortunately, neither of these guidelines contained any reference to genetic research. The World Medical Association (WMA) issued the historical predecessor of the Declaration of Helsinki in 1954 and the first draft of this was published in 1964. Since then, the declaration has been revised five times. Although the most important ethical issues about research on human patients were discussed in the last version of the declaration, certain ethical considerations concerning genetic research have been excluded. These include gene therapy, privacy of genetic

information, sex selection, cloning, eugenics, patent and licensing and others. Respect for persons, beneficence, justice, informed consent, disclosure of information and volunteerism are some of the topics debated in The Belmont Report, issued by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

The US Department of Health and Human Services (DHHS) issued the DHHS Regulations for the Protection of Human Subjects in 1991. The document includes detailed explanations regarding important bioethical terminology. In addition, it outlines the role of the Institutional Review Boards (IRB) in supporting patients undergoing biomedical research. These include the requirements and documentation for informed consent and maternal-fetal rights during pregnancy. The Summary Report of the International Summit Conference on Bioethics towards an International Ethic for Research involving Human Subjects of 1987 addressed the growing importance of international agreements and cooperation on both the

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elaboration of principles and on the implementation of ethics review processes in medical research involving human subjects. The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization issued a series of guidelines for biomedical research involving human subjects in 1993. No particular bioethical consideration in the area of genetic research can be found in this document.

In short, we believe that discussions on ethical topics relating to genetic research should be included in the international bioethical guidelines.¹

Important bioethical issues under debate

Gene therapy

Innovations in recombinant DNA research in the early 1970s and in vitro fertilization in the 1980s brought closer the prospect of genetically manipulating human eggs, spermatozoa and embryos. Various ethics committees have been set up in developing countries to assess ethical issues associated with embryo research, reproductive technologies and genetic manipulation. Gene therapy has two streams: somatic cell gene therapy and germline gene therapy. Considering the ethical aspect of these therapies, germline gene therapy is the most relevant. National and international governmental and non-governmental organizations have reached a range of conclusions about the ethical acceptability of germline gene therapy.²⁻⁴

Privacy of genetic information

In a strict sense, genetic data is information about the genetic code of the human chromosomes present in the nucleus and mitochondria of the cells of an individual. It also refers to the number and gross state of the chromosomes. It is this genetic data that determines the individual's genetic identity.

In the legal context, the term "privacy" includes at least four categories: 1) access to persons and personal spaces; 2) access to information by third parties and any subsequent disclosure of this information by third parties; 3) third-party interference with personal choices, especially in intimate spheres such as procreation; and 4) ownerships of materials and information derived from persons.⁵ What is important is that the highly personal nature of the information contained in DNA can be illustrated by thinking of DNA as containing an individual's "future diary".

DNA databanks can be assumed as entities that collect, store, analyze and control DNA samples and information derived from DNA samples, although the term could also include entities that either only store DNA samples or information derived from genetic analysis. Therefore, to effectively protect genetic privacy, unauthorized collection and analysis of individually identifiable DNA should be prohibited. DNA samples or genetic information about an individual should not be stored unless that individual specifically authorizes the collection of DNA.

Sex selection

There are many differing attitudes toward sex selection before birth. While liberals support sex preselection as morally acceptable in family planning, others condemn any type of sex selection. The popularity of having either a son or daughter among families may lead to sex-ratio changes. New methods of preselecting sex will probably be introduced over a period of several decades. Thus, there will be time to improve our understanding of the consequences in affecting the sex ratio.

Cloning

The world of science and the public at large were both shocked and fascinated by the work of Wilmut and colleagues when they successfully cloned a sheep, in spite of the global consensus against cloning.⁷ The National Bioethics Advisory Commission is reviewing the ethical and legal implications of cloning in the USA. The Director General of the World Health Organization characterized human cloning as "ethically unacceptable" as it would violate some of the basic principles which govern medically assisted reproduction. These include "respect for the dignity of human beings and the protection of the security of human genetic material".⁸ As in the USA, one can not see a firm acceptance of cloning throughout the world.⁵ Despite this negative sentiment, biotechnologists can understand the personal and social benefits of cloning such as allowing women who have no ova or men who have no sperm to produce offspring that are biologically related to them.⁹

Eugenics

According to Francis Galton, eugenics is the science of improving human heredity over time.¹⁰ Sterilization is the main topic discussed in the field of eugenics. Despite major opposition to

Bioethics in Iran: Legislation as the Main Problem

sterilization laws from the Catholic Church, as well as Islamic conservatives and some other religions, sterilization is otherwise globally accepted.

Patents and licensing

The collection, treatment, storage and use of genetic data are other issues troubling ethicists around the world. Tens of thousands of applications for patents on human genes, living cells, plants and animals have been made in recent years, and hundreds of them have been granted, especially in the USA and Japan.

Should it be legal to patent genes and traditional knowledge? This is a very important question that remains to be answered by authorized organizations. Somehow the source of genetic data indicates the status of property in each case. If the material was obtained from a nonhuman source, the law generally considers it as property. In contrast, if the material was obtained from a human source, the law generally does not recognize it as property. It has been recognized that a living organism not naturally occurring but rather created by the intervention of humans is a product of invention and not a product of nature.¹¹ Artificial living organisms in the USA qualify for patents under US patent law.¹²

Numerous amounts of information are available from massive sources such as the Human Genome Project; however, biologic studies occur around the world. Hence, patent laws for obtaining information directly from patients and/or institutions should be clarified by each individual government.

Current bioethics organizations in Iran

Current bioethics organizations in Iran include The Ministry of Health and Medical Education, Office of Study for Humanistic and Islamic Science on Medicine and Medical Ethics. This office drafted a 27-clause act entitled "Protection Code of Human Subject in Medical Research". Included in this Act were the most important ethical considerations such as informed consent, human rights during research, certifying research projects according to risks and benefits, privacy of information, compensation of human subjects under investigation, sensitivity to cultural and religious implications, observing the rights of prisoners and individuals with mental illness, and conducting research on fetuses. Besides the Helsinki Declaration and the documents of CIOMS, which constitute the scientific basis of the

Act, the document has been customized according to Code of religious laws in *Shia* (the official religion in Iran) and peculiar cultural issues of the Iranian population. An informed consent in the form of a validated questionnaire has been attached to the Act.¹³

All universities and biomedical research centers in Iran were recently required by the Ministry of Health and Medical Education to develop bioethics committees based on a uniform guideline. The guideline was prepared by the office of Deputy Research, Ministry of Health and Medical Education.

The Iranian National Commission for UNESCO is another bioethics organization in Iran. This organization is drafting a 16-clause guideline for constitution of a national bioethics committee. It aims to resolve some issues such as priority setting of national bioethical studies, coordinating all ministries, organizations, universities and research centers with bioethical issues, solving the problem of higher education in the field of bioethics, establishing a reasonable base for international negotiations in this area of science and trying to draw the financial resources toward the research projects on bioethics. A delegation from the Ministry of Science, Research and Technology, Ministry of Health and Medical Education, Organization for Protection of the Biologic Environment, Ministry of Agricultural Jihad, Legal Medicine Organization of Iran, Hozehe Elmieh of Qom (Qom Seminary), Iranian Academic Center for Education, Culture and Research (ACECR) and Medical Council of the Islamic Republic of Iran (as an NGO) constitute the permanent members of the committee. Other permanent members include: two specialists in philosophy and ethics, two lawyers, two biotechnologists, two biologists, and one specialist each from the fields of immunology, genetics, pharmacology, biochemistry psychology and epidemiology.¹⁴

Finally, bioethics organizations are also present in Research Centers: local ethics committees have been established in over 85 research centers involved in biotechnology, molecular and cellular biology and related fields, and the number of these centers is increasing. Some of these centers, including the Research Center for Gastroenterology and Liver Disease and the Avcina Research Center, have developed an article of association and also standard inquiries for certifying research proposals on genetics.

Meanwhile, the Molecular Medicine Network

is a new organization which coordinates and supervises the research center laboratories involved in molecular and genetic research. The current trend is to write a uniform guideline for ethics committees of all these centers supervised by the Network.

Potential sources of bioethical laws in Islam and Shia

1- Islam

The modification and improvement of living organisms and the creation of microorganisms through biotechnologic means challenges all religions, including Islam. It attempts to refine their doctrines and expand their ethical imagination. In Islam, bioethical decisions are based on the ethical teachings of Qur'an, the tradition of the Prophet Muhammad and the interpretation of Islamic law. Islamic bioethics is an extension of *Shariah* (Islamic law), which is itself based on two foundations: the Qur'an (the holy book of all Muslims) and the Sunna (the aspects of Islamic law based on the Prophet Mohammad's words or acts). Consensus (*ijmaa*) and analogy (*qiyas*) are two other sources of Islamic law. In addition, consideration is given to *maslaha* (public interest) and *urf* (local customary precedent) where appropriate. The *Shia* branch of Islam has in some cases developed its own interpretations, methodology and authority systems, but on the whole its bioethical rulings do not differ fundamentally from the Sunni position.¹⁵⁻¹⁷

In short, Islam places no limitations on the pursuit of scientific knowledge, including genetics. According to Hathout and Lusting, there is a consensus among Islamic scholars that a governmental rule that refers to "changing God's creation" does not support a ban on genetic engineering. They concluded that genetic engineering is permissible.¹⁸ However, Serour restricts the justifiability of gene therapy to its therapeutic uses since using biotechnology in genetic research for eugenic purposes would involve a change in the creation of God's creation, which would cause imbalance in the universe or humanity.¹⁹

2-Shia

As mentioned above, *Shia* is a branch of Islam. although approximately one-fifth of Iranians belong to the Sunni branch of Islam, *Shia* was the historical religion of the Iranian population nine to

10 centuries ago. *Aql* (the process of reasoning) and *urf* (custom) are two other important sources of drawing Islamic law.

Shia jurists have formally recognized *aql* as an independent source of the Islamic law and have examined it in detail with the strong support of jurisprudence. The role of community practice (custom) as a supplementary tool in the process of inferring the Islamic law, is in principle, undeniable. Historically, relying on *aql* (literally, the act of withholding or restraining and, in terminology of the jurists, human intellect or reason) as a source of inferring the Islamic laws takes us back to the early centuries of Islamic law development.²⁰

Comment

Today, all human beings should be able to benefit from the positive and valuable results of this scientific development. Hence, with the cooperation of the international community, principles and regulations should be adopted to guarantee the freedom of research, allowing scientific progress while at the same time safeguarding the rights and dignity of human beings.

Iran has an ancient history and throughout its historical past of biologic and geographic diversity, has also hosted various ethnic groups who still retain their own cultural identities, while enjoying equal rights. While preserving their own special culture as well as social, architectural, linguistic and civilization characteristics, they have also contributed to the process of dialogue among civilizations.²¹

Similar to other parts of the world, a great majority of intellectuals in Iran make claim on the protection of bioethics laws when representing international intellectual societies. However, one cannot deny the real religious nature of attitudes and beliefs of the majority of the population in the country. We believe that the outcome of international conventions and or conferences may only result in only a few or even no modifications from the Iranian government and the religious legislators of the country.

Fortunately, among the many bioethical controversial issues, only abortion is banned outright in Iran. However, under exceptional circumstances, such as endangerment of the mother's life abortion is authorized. Allograft transplantation constitutes a legal action at present, and the legal issues concerning the transfer of

Bioethics in Iran: Legislation as the Main Problem

sperm from a non-spouse donor are under intense investigation.

We look forward to collaborating and cooperating with international bioethical communities to share and witness development and progression of modern bioethical committees and legislations.

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