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Biotechnology, Bioethics and National Ethical Guidelines in Biomedical Research in Iran

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Abstract: Rapid advances in biotechnology and science are resulting in an ever-increasing demand for global responses to the related ethical issues. These advancements could lead to irreversible disasters if not limited by ethical guidelines. In the last decade, there has been a special attention focus on biotechnology development and bioethics empowerment in Iran. In this paper we aim to review the situation of biotechnology in Iran. The main national bioethical activities will be addressed. We also discuss the "National Ethical Guidelines of Biomedical Research", including 'genetics research' and 'gamete and embryo research' which have been compiled recently.

***Keywords*:** Bioethics, medical ethics, biotechnology, ethical guideline, Genetics, gamete donation, embryo donation, Islam, Iran.

Introduction

Biotechnology has confronted the world with some bioethical challenges which have raised numerous questions with no definite answers. Genetic engineering, genetic manipulations, genetic testing, gene therapy (somatic cell and germ cell), eugenics, selective abortion, genetically modified foods, behavioral genetics, new Assisted Reproductive Technologies (ARTs), stem cell research and cloning are some of the most important issues. The ultimate goal is to use these technologies to

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develop new ways to treat, cure, or even prevent thousands of human diseases. However, these developments have raised ethical and societal concerns about how resulting technologies will be implemented, and about how their implementation will impact different communities. Amongst all, concerns about subjects' rights, informed consent, privacy, patenting and ownership of genetic material, development of biobanks, forensics, the commercialisation of products including property rights and accessibility of data and materials require special global attention. Consequently, many attempts have been made by scientists, ethicists, jurisprudents and lawyers for compiling international and national guidelines for the regulation of and legislation in this field in recent decades.

Iran, with a long history of science and with great scholars, scientists and philosophers, has played an influential role in world civilization. The great Iranian scientists have paid special attention to ethical insights in the scientific realm.[1] The recent International Congress of Bioethics in Iran (2005) was a major step forward in reaching an agreement on the important issue of bioethics[2] it was a step towards reaching an agreement for the final declaration of bioethics.[3] The Tehran Statement[4] clearly showed that the international community is aware of the hazards and the benefits of biotechnology, and is willing to accommodate all facilities to use this robust science in the right way and to impede any possible abuses.[5]

In this manuscript we aim to present the biotechnological situation pertaining to Iran and to address some bioethical activities in this field. Likewise, we also intend to mention the "*National Ethical Guidelines of Biomedical Research*", including 'genetics research' and 'gamete and embryo research' which have been compiled recently.

Biotechnology in Iran

Iran is one of the pioneers of biotechnology in the Eastern Mediterranean region. In this area, the Pasteur Institute of Iran and Razi Institute both have more than 70 years' experience in conventional biotechnology. The Pasteur Institute of Iran has been acting as a national centre of infectious diseases diagnosis and vaccine production since 1920.[6] Molecular biotechnology started from the Biotechnology Department at the Pasteur Institute of Iran and the National Research Centre for Genetic Engineering and Biotechnology (NRCGEB).[7] The NRCGEB was established in 1988 under the supervision of the Ministry

of Science, Research and Technology.[8] The major activity of NRCGEB in the area of medical biotechnology is concentrated on human genetic disorders, recombinant protein and heterologous gene expression. The Biotechnology Department of the Pasteur Institute of Iran (1993) was officially entitled Biotechnology Research Centre (BRC) in 1997.[9] Likewise, an organization called the Iranian Biotechnology Society (IBS) was founded in Iran in 1997 that has more than 350 members at present.

In recent decades, Iranian policymakers tried to facilitate the infrastructure movement in the area of modern biotechnology. Some important governmental bodies related to biotechnology in Iran are: the Supreme Council in Biotechnology, 2005 (under supervision of the President), the Technology Cooperation Office of the Presidency, Medical Biotechnology Committee, 1998 (the Ministry of Health and Medical Education), the National Medical Biotechnology Network, 2002 (Deputy of Research and Technology, Ministry of Health and Medical education), the High-tech Industry Centre, 2001 (Ministry of Industry), the Iranian Molecular Medicine Network, 2001 (34 research institutes and centers joined as members), and the Regional Health Genomics and Biotechnology Network, 2004 (Eastern Mediterranean Region, including centers from Jordan, Kuwait, Morocco, Oman, Pakistan, Saudi Arabia, Sudan, Syrian Arab Republic, and Tunisia).[10]

A long-term plan for the national biotechnology policy was prepared in 2004 in which different aspects of biotechnology in terms of education, research, production, and international relations have been defined.[11] Recently, the Ministry of Health and Medical Education (MOHME) has allocated a substantial grant specifically for biotechnology in all universities. This special grant reveals the overwhelming importance of biotechnology in the current 5-year plan of national development.[12]

The research activity and importance of biotechnology had a strong impact on the progress of this field in the country. More than four recombinant proteins in the area of bio-pharmaceutics are either produced or are in the process of obtaining permission to market. A wide variety of recombinant proteins for molecular biology and molecular diagnostic kits have been produced by private companies. A recent trend toward the export of biotechnology products manufactured by private companies has started.[13] It is noteworthy that some Iranian biotech products have been exported to Europe, South America, India, Egypt and Pakistan.[14]

Bioethics in Iran

Great Iranian physicians had paid special attention to ethics in their practices, teachings and manuscripts during different centuries.[15] Investigations into the medical ethical values of ancient Persian culture have proved more fruitful.[16] Zoroastrian priests had special emphasis and supervision on physicians' practice.[17] After Islam, inspired by Islamic teachings, Muslim physicians have placed emphasis on ethics in their practice. Given the religious emphasis on moral virtues, most of the famous medieval Muslim physicians would devote part of their books to medical ethics.[18] For instance, *Abu al-Hasan Ali ibn-e Raban Tabari* (AD 807-861), described in the book *The Paradise of Wisdom* (*Ferdous al Hekmat*) the Islamic codes of ethics.[19] *Mohammad ibn-e Zakariyya Razi* (AD 865–925) has also wrote some manuscripts on principles of medical ethics, and his book *Spiritual Medicine* (*Teb e Rohani*) is about ethics.[20] *Abu Ali al-Husayn ibn Abdahhah ibn Sina* (Avicenna, AD 973-1037), the well-known physician of the Islamic era, in his medical books has comprehensive moral advices about clinical medicine and physicians' practice.[21] Likewise, the ethical recommendations of *Ali ibn Abbas* Ahwazi (*Haly Abbas*, 930-994) to physicians, known as *Ahwazi Advises*, highlighted the ethics of medicine.[22] For thousands of years, ethics have been recognised as an essential requirement in the making of a physician in Islamic and Persian medicine.[23]

An emphasis on ethics has been voiced by medical and religious authorities in recent decades in this country.[24] A review of activities has been published in the *Eastern Mediterranean Health Journal*.[25] The compilation of a strategic plan for medical ethics activities was carried out in 2002 by the Research and Technology Deputy of the Ministry of Health and Medical Education.[26] The establishment of Medical Ethics Research Centre (1993, MOHME), organising the first International Congress of Medical Ethics (1993), development of Medical Research Ethics Committees at national level (1997), establishment of Medical Research Ethics Committees at universities and medical research centres, compiling and implementing the National Code of Ethics in Biomedical Researches all over the country have been its main activities in recent years.[27]

In recent years, professional education of medical ethics through MPH courses and periodical seminars and workshops in different regions of the country has been enhanced. Institution of PhD courses in

bioethics is one of the future plans of MOHME. The Islamic Republic of Iran put forward the proposal of a special award in the name of 'Avicenna' in the field of ethics in science and technology to UNESCO, which was later adopted by this international institute (UNESCO). The Award consists of a gold medal of Avicenna (see Fig. 1) along with a certificate (the sum of $10,000) and a one-week academic visit to Iran. The winners of this award were chosen and introduced in 2004 and 2006.[28]

Fig1. The Avicenna gold medal.

As a result of the collaboration of scholars, scientists, experts, and those interested in the progress of bioethics in science and technology and making use of the immense national heritage and religious teachings, the Iranian Association of Ethics in Science and Technology was established in 2005.[29] It was an important step towards the closer collaboration of science and ethics in Iran.[30]

National Ethical Guidelines in Biomedical Research

Compiling the Specific National Ethical Guidelines for Biomedical Research was an important effort, undertaken as a joint project by the Medical Ethics and Medical History Research Centre (MEHRC), the Deputy Minister of Research and Technology of MOHME, and the Endocrinology and Metabolism Research Centre (EMRC) of the Tehran University of Medical Sciences (TUMS) in 2005. These Specific National Ethical Guidelines for Biomedical Research consist of: *Ethical Guidelines for Clinical Trials*, *Ethical Guidelines for Research on Minors*, *Ethical Guidelines*

for Genetic Research, *Ethical Guidelines for Gamete and Embryo Research*, *Ethical Guidelines for Transplantation Research*, and *Ethical Guidelines for Research on Animals*. Similar guidelines and references from other countries are used in the initial compilation of these guidelines. The guidelines were reviewed and adopted by some law, ethics, medical and religious experts and the authorities of the Policy-making Council of MOHME.

The *Ethical Guidelines for Genetic Research* (see Annexure 1) and the *Ethical Guidelines for Gamete and Embryo Research* (see Annexure 2) are two important guidelines that should be taken into account in the field of biotechnology.

Considering the relatively high prevalence of genetic disorders in the country, there is a clear need for an organized development of services for these disorders with appropriate ethical supervision. Medical genetic ethics has been considered by Iranian specialists in recent years.[31] Currently, there is no absolute restriction on genetic research in Iran; however moral principles and ethical codes must be completely followed. Based on the *Ethical Guidelines for Genetic Research*, permissibility of genetic researches depends on the purposes (see Annexure 1). Moreover, prenatal diagnosis is permissible only if it is concerned with mother or foetus health, eugenic researches are prohibited. When a genetic testing is considered, a culturally adapted genetic counselling should be provided in an appropriate manner. In any kind of genetic researches, the best interests of the person concerned must be taken into consideration.

According to religious decree, human reproductive cloning is not permitted. Iran's Muslim Shi'a religious leaders have issued decrees authorising animal cloning. However, stem cell research and cloning for therapeutic purposes is permissible with full consideration and all possible precautions only in pre-ensoulment stages of foetus development.[32] Consequently, Iranian researchers of the Royan Institute reported the derivation of a new embryonic stem cell line (Royan H1) from a human blastocyst about two years ago.[33]

Abortion is a main issue of debate on the subject of prenatal genetic testing. The Parliament of the Islamic Republic of Iran approved a new Act on Abortion on 21 June 2005.[34] Previously, religious scholars had been allowed abortion in untreatable and genetic disorders with 3 criteria: definite diagnosis, before 4 months of gestation, and unusual

problems for family. Under the new law, a pregnancy can be terminated within the first four months of pregnancy if the foetus is mentally or physically handicapped, or where the mother's life is likely to be in danger.[35]

Conclusion

As bioscience grows, a parallel structure grows with the same strength to provide assurance for people who are worried about negative applications or abuses of such growth.[36] In Iran, since capacity building in medical biotechnology has been the goal of different policy makers in last decade, we have been facing a good movement in biotechnology.[37] Now, appreciating all our scientists' efforts in the field of bioethics, appropriate ethical and scientific supervision of biotechnological programs should be enhanced to make sure that these advances are used responsibly, fairly, and humanely.

In the first step, ethics education for scientists and improvement of public awareness are essential for better mutual understanding of ethical challenges in the society. Addressing some ethical issues requires a continuing dialogue and cooperation between physicians, researchers, and religious scholars. Certainly, the biomedical and religious professions must be better prepared to deal with the increasingly complex issues in these fields. Certainly, socio-cultural backgrounds should be considered and reflected in the structuring and adaptation of the ethical guidelines and legal rules.

Endnotes

1 Larijani (2006a).
2 MBR (2005a).
3 UNESCO (2005a).
4 UNESCO (2005b).
5 Tavangar (2005).
6 Mahboudi (2005).
7 Mahboudi (2005).
8 Mahboudi (2005).
9 Mahboudi (2005).
10 Mahboudi (2006).
11 Mahboudi (2006).
12 Tavangar (2005).
13 Mahboudi (2005).
14 Mahboudi (2005).
15 Larijani (2006a).
16 Carrick (2001).
17 Larijani (2006a).
18 Larijani (2006a).

19 Al-Ghazal (2004), Hamarnesh (1971), Levy (1967).
20 Larijani (2006a).
21 Larijani (2006a).
22 Tajbaksh (2003).
23 Amine (1981), Larijani (2006a).
24 Larijani (2006b), Larijani (2005), Akrami (2004), Larijani (2004a), Larijani (2004b), Larijani (2004c), Zali (2003), Zali (2002).
25 Larijani (2005).
26 Larijani (2006b).
27 Larijani (2005).
28 MBR (2005b), UNESCO(2003).
29 MBR (2005b).
30 MBR (2005b).
31 Larijani (2006d), Farhud (2000), Farhud (1999).
32 Larijani (2004d).
33 Baharvand (2004).
34 IR Iran Parliament (2005).
35 IR Iran Parliament (2005), Larijani (2006c).
36 MBR (2005b).
37 Mahboudi (2005).

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Annexure 1

Ethical Guidelines for Genetic Researches

Considering the ever-increasing advances in genetics, the emergence of new therapeutic technologies, and the special sensitive nature of human genetic data, and also recognising that human genetics is associated with some potential concerns regarding ethical issues, and reaffirming the importance of genetic researches for improving the public health and medicine, and recognising the importance of the ethical principles and norms, based on humanistic and Islamic foundations, and national laws in the researches of medical genetics, the ethical guidelines that follow are proclaimed for the researches in medical genetics.

The provisions in this guideline apply to the collection, processing, use and storage of human genetic data, human proteomic data and biological samples that are designed for researches. The cases of investigation, detection, and prosecution of criminal offences and parentage testing will be conducted according to the domestic law.

1. Medical Genetics Researches may be ethically permissible, only for the purposes of:
    a. Diagnosis, classification or screening of a hereditary disease or disability.
    b. Determining of vulnerability to a medical condition before emergence of its signs or symptoms, if effective interventions for reducing or preventing of its unwanted consequences are available, or the test's results are effectively and immediately related to the individual's decision-making for her/his future life or family planning.
    c. Genetic counseling for determination of the risk of hereditary diseases and disabilities in the offspring.
    d. Prevention, treatment, or palliation of diseases; and not eugenics.
    e. Forensic medicine and civil, criminal and other judicial proceedings, taking into account the domestic laws.
    f. Population-based genetic studies, taking into account the scientific and ethical principles.
2. When the collection, processing, use and storage of human genetic or proteomic data, or biological samples are carried out in two or more countries, the proposed research must be assessed and approved by the national medical research ethics committee of Iran and then by the appropriate ethics committee in the other countries concerned. It should be mentioned that the approval of all ethics committees are necessary for initiation of the research.
3. When the collection, processing, use and storage of human genetic or proteomic data or biological samples are carried out in two or more universities or research centres, the proposed research should be assessed and approved by all of their research ethics committees.

4. Every effort should be made to ensure that human genetic or proteomic data are not used for purposes that lead to discrimination or any type of infringing of fundamental freedoms or human dignity or for purposes that lead to the stigmatization of an individual, a family, a group, or communities.
5. For collecting human genetic or proteomic data or biologic samples or taking photos or videos, the consent of research participants should be free, informed, and express and without inducement by financial or other gains. The informed consent is necessary for any processing, use or storage of these data, carried out by public or private institutions.
6. In cases of incompetent people who are incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative needs to take into consideration the best interest of the person concerned.
7. An incompetent adult should as far as possible take part in the authorization procedure. The opinion of a minor, in proportion to his or her age and degree of maturity, is a determining factor and should as far as possible be taken into consideration.
8. Diagnostic and treatment services, screening, or genetic tests in minors or incompetent adults, will be ethically acceptable, only when there are definite profits for the person's health and his/her best interests are taken into consideration.
9. When human genetic or proteomic data or biological samples are being collected for medical and scientific researches, the participant can withdraw his or her consent, unless they are irretrievably unlinked to the person concerned. According to the regulations, withdrawal from the research should entail neither a disadvantage nor a penalty for the person concerned.
10. When a person withdraws consent, his/her genetic or proteomic data or biological samples should no longer be used, unless they are irretrievably unlinked to the person concerned.
11. It is ethically imperative that when a genetic testing that may have significant effects on a person's health is being considered, genetic counseling should be provided in an appropriate manner. Genetic counseling should be culturally adapted and consider the best interests of the person concerned.
12. When the research may reveal the information which has potential effects on the future of the participant or his/her family, the research protocol should include issues such as consent, counseling, support, quality of testing, and confidentiality. Otherwise, such researches should be approved only if the source of the genetic materials is irretrievably unlinked to the person concerned. Counseling and prediction of the results of research should be accomplished by appropriately trained health care workers who have sufficient experience.
13. Participants with hereditary disability or disease, asymptotic carriers of disease and also at-risk persons (proven or suspected) should receive

necessary information regarding the available diagnostic or therapeutic options for their conditions, at the appropriate time and in an appropriate manner. Furthermore, if the treatment of a participant's relatives is necessary, the researcher should inform him/her, after obtaining the consent from the participant or his/her legal representative.

14. Genetic counseling should be non-directive, free of pre-judgment and non-judgment.
15. No one should be denied access to his/her own genetic data, unless such data are anonymous or the domestic law limits such access.
16. Human genetic and proteomic data and the biological samples should not be used for a purpose different from the one mentioned in the obtained consent, except after obtaining the informed, free and express consent, or if the purposes are in conformity with domestic law and the interests of the community.
17. Researches in which obtaining of an informed, free and express consent is impossible, or data retrievably unlinked to identifiable persons, should be done only with approval of the research ethics committee.
18. Benefits resulting from the researches on human genetic data should be shared with the society.
19. Prenatal diagnostic tests should be done only if they are related with the health of the mother or her foetus.

Annexure 2

Ethical Guideline for Researches on Gamete and Embryo

Human scientific knowledge in the fields of reproductive biology and biotechnology has been greatly expanded in the two recent decades. These developments began with using the extra uterine fertilization techniques and thereafter, the Assisted Reproductive Technologies (ARTs) have been developed in a fast manner. Consequently, different ethical issues have arisen in this regard answering which requires serious and exact deliberation. Although there are different opinions regarding the status of human gametes and embryos, it is accepted that they should not be considered as mere tissues and any researches on them require obtaining the appropriate consent of the persons who are responsible for the embryo, including the donor, her partner, the recipient, and her partner (this differs from the donor).

1. Researches on the human gamete and embryo and the therapeutic plans of ARTs should be conducted with a profound respect to the human dignity of all the participants.
2. Researches on the surplus embryos of ARTs require authorization from who are responsible(s) for the embryos or their legal and juridical guardian and the research ethics committee.
3. If the research includes clinical treatment, the risk of harm should be proportionately outweighed by the benefits resulting for the participant. In researches for obtaining new information, no additive risk is justifiable.
4. Participation in the research should be completely voluntary, informed, and free of any kind of pressure. The purpose(s) of the research should not be hidden from the subjects.
5. In all research proposals, it should be mentioned that the process of informing and obtaining the consent is completely separated from the process of treatment of the patient.
6. Researchers should carefully record the information on the biological origin of the gametes and embryos. Keeping the accuracy and privacy of the information is necessary.
7. Disclosure of private information of the participants should be done only with the legal authorities' approval.
8. The participants should not bear the costs of the research.
9. Researchers should ensure that the probability of unwanted complications for the embryo or the future child is minimal.
10. The ovum or sperm used in the research should not be obtained by commercial means.
11. Production or attempts to produce hybrids using human and animal gametes, transferring of the nucleus of somatic cells or sex cells between human and animals, or any similar activities are forbidden.

12. In the cases that appropriate alternatives exist, the research should not be done on human embryos. Producing the human embryo for research purposes is forbidden.
13. Embryos that are used for producing pregnancy are not considered as surplus embryos. Research on them is acceptable only if the results could not be obtained by any other kinds of researches.
14. Researches which include destruction of the embryo should not use the embryos over 14 days of age (after conception). (The period in which the embryo was frozen, is not taken into account.)
15. In the transformation process of a human gamete or embryo to a foetus, changing the genetic content is prohibited.
16. The number of embryos that are used in research should be the minimum required for the purpose of the research.
17. Researcher should ensure the recipients that if they refuse to participate in the research, their treatment won't be influenced.
18. The embryos which are not surpluses of the ART process should not be used outside of the woman's body for purposes unrelated to the ARTs.
19. The responsible persons for the embryo are the donor, her partner, the recipient and her partner (this differs from the donor).
20. Researchers should ensure that all the information related to the research and clinical cares of the embryo are available for the responsible persons of the embryo. The explanations should be in accordance with the sensitivities and capacity of the responsible persons.
21. The responsible persons can withdraw their consent whenever they want.
22. The informed and written consent should be obtained from the couples whose embryo is to be used in the research.
23. Although the autonomy of the couples regarding donation of their embryo's tissues is respected, the mother does not have the right to make the use of these tissues exclusive for special persons, such as her family members.