

The National Ethical Guideline of Transplantation Research in Iran

*F Zahedi^{1,3}, A Parsapoor^{2,3}, M Mohaghegh-Dolatabadi³, A Jafarian³, SM Kazemeini³, *B Larijani^{1,2,3}*

¹ *Endocrinology and Metabolism Research Center, Medical Sciences /University of Tehran, Iran*

² *Medical Ethics and History of Medicine Research Center, Medical Sciences /University of Tehran, Iran*

³ *The Committee for Compiling Ethical Guidelines, Medical Ethics and History of Medicine Research Center, Medical Sciences/University of Tehran, Iran*

Abstract

Recent advances in organ transplantation have promised certain benefits to humankind. Consequently, it is necessary to take into consideration all aspects of these new approaches and provide specific ethical guidelines for research in this field. Considering the ever-increasing advancements of transplantation in Iran and noting the necessity of scientific researches in this field, and to observe ethical principles in such researches, compilation of the "National Ethical Guidelines for Transplantation Researches", as one topic of the "Specific National Ethical Guidelines for Biomedical Research" were considered in our country. We stated some points of this guideline in this article.

Keywords: *Transplantation, Ethical guideline, Iran, Foetal tissue, Living donor, Deceased donor*

Introduction

The medical advancements in science and technology have raised new ethical issues that need to be addressed. There is also a need for careful evaluation of these new methods and their outcomes through research. The inevitable necessity of standardized ethical guidelines for research on human subjects is universally recognized. For strengthening medical ethics in Iran (1, 2), scientists, ethicists, jurists and lawyers have also performed many attempts in recent decade. In the field of organ transplantation, the consensus of physicians and religious leaders has paved the way for establishing functional programs (3-5). Iran currently has one of the most successful transplantation programs in the Middle-East region. A controlled living unrelated donor (LURD) program for renal transplant was adopted in 1988 (3, 6, 7) and the 'Act of Organ Transplantation and Brain Death' was also approved by the parliament in 2000 (4, 8). It should be mentioned that there is an official program to compensate living donors by providing the so called "sacrifice gift" or "Rewarded gift". This is

accepted only as a gift from NGOs (only for kidney transplantation) and the direct commercial payments are not allowed (3, 6). Some researches are proposed to expand the organ donor pool in recent years. According to compilation of the "Specific National Ethical Guidelines for Biomedical Research" (9) in our country, transplantation researches were included as one topic. We intend to state some parts of this guideline in this article. The new guideline is about all kinds of transplantations but those are carrying out as a research, not as a treatment. There should be special guidelines, for instance; in order to use fetal tissues, deceased body, tissues provided through stem cell research, etc. The *Ethical Guideline for Transplantation Research* would be beneficial for observance of ethical principles in this kind of research.

National Ethical Guidelines

Compiling the "*Specific National Ethical Guidelines for Biomedical Research*" was done as a joint project by Medical Ethics and Medical History Research Center (MEHRC) and the Medi-

cal Ethics Group of Endocrinology and Metabolism Research Center (EMRC) of Tehran University of Medical Sciences (TUMS) in 2005. This project was supported by the Deputy of Research and Technology of the Ministry of Health and Medical Education (MOHME). The Guidelines are developed to observe ethical rules in transplantation research and to protect research participants all over the country. Some lawyers, ethicists, medical and religious experts reviewed the primary draft. These guidelines consist of *Ethical Guidelines of Clinical Trials, Research on Vulnerable Groups, Genetic Research, Gamete and Embryo research, Transplantation Research, and Research on Animals*. For preparing these guidelines, we also looked upon similar international and national guidelines in the relevant fields. In compiling the guidelines, socio-cultural issues have been taken into account seriously. The Guidelines, which the "Policy-making Council" of MOHME ratified, have been communicated to the universities and research centers by the Health Minister in February 2006.

Ethical Guidelines of Transplantation Research

Considering the multilateral approaches to advancement of transplantation programs in Iran, and noting the recent scientific movements in this regard, and emphasizing on the necessity of research in this field, observing of the ethical principles in such research is evidently essential. This guideline mentions essential ethical principles, which should be considered in the research on tissue and organ transplantation. This ethical guideline consists of two parts containing general and special articles. The topic of transplantation research has been considered with special reference to the following points:

- I. Cadaver Donor Transplantation
- II. Living Donor Transplantation
- III. Issues related to the recipients
- IV. Using organ or tissue obtained from human embryo and foetus.

According to the guidelines, all transplantation research on tissues or organs should be done

with consideration of "*the General Ethical Guidelines for Biomedical Research*"(9). Informed consent, confidentiality, compensation of any cost or possible harm to donors, intellectual property rights, safety of donors and recipients are the most important principles mentioned in the general part of the guideline. Purpose of research should be scientific advancement and in accordance with goals of national health system, and should not be for financial or commercial purposes. For using the tissues or organs of foreigners in transplantation research, the approval of the "National Research Ethics Committee" is necessary (article 13, Note 2).

Considering the shortage of organ and tissue for transplantation in Iran, the therapeutic uses should take priority and research uses should not reduce the rate and quality of the therapeutic transplantation (article 15). For using tissues and organs stored in the banks, the donor should mention his/her consent for this kind of use (article 16). The system of obtaining consent for using cadaver for research in Iran is opting-in. Therefore, the consent of person before death or the consent of his/her representative (decision maker) is necessary (article 1-1). Moreover, at the time of removal of tissues or organs from cadaver until the time of burying cadaver, observance of customary and spiritual respects to cadaver and the removed tissues or organs is essential (article 1-4). Research on living donors should be restricted to renewable tissues like bone marrow (article 2-2). In the cases of absolute necessity, under observance and approval of ethical committee of the university, one can use pair organs whose removal will not greatly alter the physiologic functions, for research purposes. The donor should be lifetime insured and all of the related harms should be compensated (article 2-2, Note1).

Surplus or waste tissues remained from diagnostic and therapeutic procedures or surgeries, by considering confidentiality and after approval of ethics committee, can be used for transplantation research, without obtaining an informed consent, unless prior notification of owner's dis-

agreement (article 2-4). Based on the guidelines, research with human subject should be covered by insurance (article 2-6, Note1).

Financial incentives or special advantages should not be used for encourage persons for organ or tissue donation in the transplantation research with living donor (article 2-8). Moreover, children, mentally retarded or mentally disabled persons, psychiatric patients and other special groups, who possibly have not competence for informed decision making, should not be tissue or organ donors in transplantation research (article 2-9). These groups, should only be recipient of tissue or organ in transplantation research with direct therapeutic benefit for them (article 3-2). If the recipient is a patient who needs organ or tissue, the best available therapeutic methods should be used for him/her and access to treatment should not be banned for research purposes (article 1-3).

Human fetal tissue could be used in transplantation research for a wide range of purposes. The use of fetal tissue will minimize the chance of rejection. However, the transplantation research on tissues or organs of embryo or foetus should be approved by the "National Committee of Research Ethics" in keeping with the national guidelines (article 4-1). Such researches are only permitted in the public universities or research centres and under surveillance of the Ministry of Health and Medical Education (article 4-1, Note1). For using the organs and tissues of foetus in the transplantation research, scientific approval of the research and follow up, control and subsequent assessments by the research institute and related authorities are necessary (article 4-2). In addition, animal experiments must show successful results (article 4-2). Such trials in human patients will commence only on those patients when no other form of treatment is available and in the absence of the transplant, the patient is likely to suffer relentless deterioration in his/her health with fatal termination. It has emphasized that trials should be carried out only at institutions having appropriate facilities needed for performing such researches (article 4-2).

For avoidance of slippery slop in using foetal tissues, specialists who approve abortion should not be the member of the research group who subsequently uses the embryonic or foetal tissues (article 4-11). Persons who have not related to the organization in which the research is being conducted (article 4-12) should make decision-making regarding abortion. In other words, creation of human beings for transplantation purposes has been banned. Screening of transmissible diseases between the donor foetus and his/her mother is necessary (article 4-13). Financial relationship between the donor and the recipient in the research on transplantation of organs and tissues of embryo or foetus is forbidden (article 4-14).

The National Committee of Research Ethics for optimal use of available tissues and organs (article 4-18) should do priority-setting regarding the research on transplantation of organs and tissues of embryo and foetus.

Paucity of organs from humans for transplantation into other humans has led to search for other sources such as animals. There was another part concluding xeno-transplantation in primary draft of this guideline, which eliminated because of the existence of the Guidelines of Research on Animals.

Conclusion

Historical evidences of non-observance of human rights in research participants have led to paying special attention to research ethics and providing international ethical guidelines in this field in recent decades. Meanwhile, in some countries, national ethical rules and guidelines have been compiled according to their socio-cultural and religious beliefs (10- 12). Compiling the Specific National Ethical Guidelines for Biomedical Research in our country is unique in the region, but with no doubt, there should be continuing efforts for conducting guidelines and putting the guidelines into practice. Systematic control and strengthening research ethics committees all over the country would pave the way for achieving the goals in the coming years.

References

1. Larijani B, Malek-Afzali H, Zahedi F, Motevaseli E (2006). Strengthening Medical Ethics by Strategic Plan in Islamic Republic of Iran. *Dev World Bioeth*, 6(2):106-10.
2. Larijani B, Zahedi F, Malek-Afzali H (2005). Medical ethics activities in Iran. *East Mediterr Health J*, 11(5/6):1061-72.
3. Larijani B, Zahedi F, Taheri E (2004). Ethical and legal aspects of organ transplantation in Iran. *Transplant Proc*, 36(5):1241-44.
4. Akrami SM, Osati Z, Zahedi F, Raza M (2004). Brain death: recent ethical and religious considerations in Iran. *Transplant Proc*, 36(10):2883-87.
5. Ghods AJ (2002). Renal transplantation in Iran. *Nephrol Dial Transplant*, 17(2): 222-28.
6. Larijani B, Zahedi F, Ghafouri Fard S (2004). Rewarded gift for living renal donors. *Transplant Proc*, 36(9):2539-42.
7. Larijani B, Zahedi F, Taheri E (2006). Deceased and Living Organ Donation in Iran. *Am J Transplant*, 6(6):1493-93.
8. IR Iran Parliament (2000). Deceased or Brain Dead Patients Organ Transplantation Act. H/24804-T/9929, 4 June.
9. Medical Ethics and History of Medicine Research Center (MEHR) (2005). The National Ethical Guidelines (in Farsi). Available from:
<http://mehr.tums.ac.ir/Codes.aspx>
10. The UK Medical Research Council (2001). MRC Ethics Series: Human Tissue and Biological Samples for use in Research: Operational and Ethical Guidelines. Available from:
www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420
11. Indian Council of Medical Research New Delhi (2000). Ethical Guidelines for Biomedical Research on Human Subjects. Available from:
<http://icmr.nic.in/ethical.pdf>
12. National Health and Medical Research Council (NHMRC, Australia) (2007). Human Research Ethics Handbook: National Statement on Ethical Conduct in Human Research. Available from:
www.nhmrc.gov.au/publications/synopses/e72syn.htm