

National bioethical legislation and guidelines for biomedical research in the Islamic Republic of Iran

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Abstract Rapid advances in biomedical science and technology, which have revolutionized medicine and health-care services in different societies, have been associated with inevitable ethical challenges. Undoubtedly, these innovations could lead to irreversible disasters if they are not limited by appropriate regulations.

Substantial attempts have been made in the Islamic Republic of Iran to establish a structured approach for identifying, analysing and resolving ethical issues in clinical practice. Given the consensus of religious and scientific scholars, some laws recently approved by the parliament include the Deceased and Brain-Dead Patients Organ Transplantation Act (2000), Embryo Donation to Infertile Spouses Act (2003) and the Therapeutic Abortion Act (2005). National guidelines for ethical assessment and supervision of research proposals have also been compiled by the authorities. This paper reviews the main endeavours made in bioethics legislation in the Islamic Republic of Iran.

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Introduction

In recent decades, great attention has been paid to ethical issues as an inevitable consequence of emerging biomedical advances. There have been ever-increasing discussions about ethical aspects of this new knowledge in different societies. Accordingly, the propensity in scientific society to look for legitimate solutions to moral dilemmas has led to the involvement of bioethics with the law. Some countries now have rulings and guidelines on bioethical concerns, although legislation in some challenging cases such as cloning has produced controversies.

The academic efforts of bioethicists to address these modern dilemmas has provided crucial assistance to both political and professional societal leaders.¹ Organizations such as WHO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) have recognized the necessity for creating specific guidelines to protect human rights in health-care settings. The principal issue involved is the influence that various sociocultural and religious backgrounds exert in different countries. UNESCO's Global

Ethics Observatory (GEObs) initiative is a resource of databases that encourage international collaboration and provide support to all interested parties.²

Bioethics empowerment and legislation have received special attention in the Islamic Republic of Iran. The most important recent efforts have been the enactment of regulations covering new fields of science and technology and the compilation of *The ethical guidelines for biomedical research*. We will review these endeavours and the legislative process. First, we intend to elucidate the religious background of our country, which is very important for understanding and practising bioethics in the Islamic Republic of Iran.

Values and principles

In the Islamic Republic of Iran, in which Shi'a Muslims are in the majority (80–90%), ethical issues are discussed among medical physicians and religious scholars. The main rules of activities consist of the holy Quran and principles of Islamic ethics; the religious opinions (*Fatwa*) of Islamic scholars on special issues; the national laws or ethics codes; international guidelines; and the

norms of the society. Since minority groups such as Sunni Muslims and Armenians are represented in the parliament, their opinions are also considered in religious discussion. On account of the fact that there is a diversity of opinions among different religions, all Iranians, Muslim or non-Muslim, are permitted to follow their religious beliefs providing that they are not against the law. For example, concerning contradiction over cadaveric donation, brain-dead organs will be donated only if there is valid consent of the deceased and his/her family.

Although the main principles of "western" bioethics (autonomy, beneficence, non-maleficence and justice) are acceptable according to Islam,³ interpretation of them can differ. For example, there is a limit on autonomy; sometimes the interest of the society is preferred to individual rights.

In Muslim countries, in any discussion on bioethics, there is a tendency to look towards religion. Islam is believed to be able to fully restore the harmony between religion and science.⁴ The principles of bioethics and solutions to ethical problems are therefore derived from the Islamic legal rulings.

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The main principles of Islamic ethics are the respect for human dignity, eternity of life (immortal soul and life after death), altruism, benevolence to fellow human beings, seeking perfection and eternal salvation, and association of a human being with God and the universe. It is noteworthy that there is a wide overlap between Islamic bioethics, the Islamic rulings (*Fegh* or *Shari'a*) and law, so that some religious principles such as eternity of life or seeking perfection could be very important in ethical decision-making in an Islamic setting. For instance, in the issue of the end of life, suffering a lot of pain cannot justify ending life in terminally-ill patients who believe in resurrection.⁵ According to Islamic teachings, pain has an educational purpose and is a means to self-purification after sinful behaviour.⁶ As another example, the Islamic view about when life begins has been used by Iranian jurists for issuing *Fatwas* on allowing stem cell research and cloning for therapeutic purposes. In keeping with the teachings of Islam, this kind of research is permissible only in “pre-ensoulment” stages of fetus development, i.e. up to 120 days after conception.

At the same time, jurisprudence in Islam is reached through a process of analysis and reason by religious scholars who determine the acceptability of best practice.⁷ In Islam, there are primary rules in general practice (such as fasting during the month of Ramadan) which should be fulfilled by all Muslims. There are secondary rules for special situations (for instance, dispensation of fasting due to pregnancy or illness). Both the primary and secondary rules are taken into consideration in the process of *ijtehad* (the issuing of decrees by religious leaders). Therefore, sometimes an obligatory religious law can be disregarded in special circumstances. This dynamic quality means that Islam can easily adapt to new innovations in science and technology. Inspired by Islamic teachings, Muslim scientists have proposed some well-known Islamic principles to consider for ethical decision-making,⁸ such as the principles of “the public interest” (*Maslaha*) and “do no harm” (*La Darar wa la Derar*).⁹ This dynamic jurisprudence has paved the way for approval of some laws in the field of medical ethics in the Islamic Republic of Iran.

Bioethics legislation

In addition to the long history of medical ethics in the Islamic Republic of Iran, there has also been great emphasis on contemporary bioethics in the current era.^{10–12} Development of the National Committee of Medical Research Ethics in 1997 paved the way for the establishment of medical research ethics committees in medical universities and research centres nationwide.¹¹ Over recent years, educational courses, workshops and conferences have played an important role in strengthening research committees. The establishment of a Masters in Public Health in medical ethics has provided the country with human resources for ethics committees.

Implementation of the National Code of Ethics in Biomedical Research in 2000, prepared by the Ministry of Health and Medical Education (MOHME), was another preliminary step in this field. The code, which includes 26 articles, is in accordance with international declarations and Islamic codes.¹¹ Likewise, in 2002, the research and technology deputy minister of the MOHME began the project of the Strategic Plan for Medical Ethics Activities which governs major areas of management, regulations, communications, research, education, training, public announcement, monitoring and assessment of medical ethics activities at the national level.¹³

In recent years, considering positive viewpoints of religious scholars about bioethical issues such as organ transplantation, abortion, assisted reproductive technologies (ARTs) and stem cell research in the Islamic Republic of Iran, the parliament has ratified some laws related to bioethics, including: the Deceased and Brain-Dead Patients Organ Transplantation Act (2000), Embryo Donation to Infertile Spouses Act (2003) and the Therapeutic Abortion Act (2005).

In fact, legislation in the field of bioethics has been mostly based on sacred sources (such as the Holy Quran) and the specific decrees of the Muslim scholars. Taking into account technological advancements in terminal care, the parliament approved the Deceased and Brain-Dead Patients Organ Transplantation Act in 2000.^{14–17} The process of ratification was too long because of a wide disagreement about the subject.^{16,17} According to the act, ca-

daver organs and brain-dead persons are used for transplantation according to the will of the dead person or the consent of his/her family and the definite confirmation of brain death by specialists. To make the act more practical and useful, organ-donor cards were provided and distributed nationwide. All volunteers sign a card and choose the organs to be donated after their death. As a result of this initiative, the rate of cadaveric renal transplantation increased by 40%.¹⁸ According to the MOHME, while only 32 cadaver renal transplants were carried out in 2000, this figure rose to 245 in 2006.^{18,19}

Different methods of assisted reproduction have raised ethical and religious disputes worldwide. There have been major technological achievements in the area of infertility treatment including third-party reproduction in the Islamic Republic of Iran. There is a more open-minded view of ARTs in the Islamic Republic of Iran than in many other Muslim countries.⁷ Taking into account the substantial requests of infertile couples, the Iranian parliament approved a law entitled Embryo Donation to Infertile Spouses Act in 2003.^{20,21} Under the new law, the donation of an embryo is permitted under certain conditions. The *Fatwa* of the Iranian religious leader was crucial in the attempt to draw up legislation to regulate the clinical practice of embryo donation. The act has been very helpful to prevent the break-up of many marriages in recent years, though there is no published data. ART treatment costs are high in general, although the costs in the Islamic Republic of Iran are much lower than in many other countries. Due to this, the Supreme Council of Insurance is considering covering the cost of one cycle of ART treatment.

The parliament of the Islamic Republic of Iran also ratified the Act of Therapeutic Abortion in 2005.^{22,23} Abortion causes many emotive debates in the field of medical ethics because of the different cultural and religious beliefs in various societies. Under the new act, therapeutic abortion would be permissible within the first four months of pregnancy after confirmation of it by three experts and verification by the Legal Medicine Organization. The law would allow abortion to be performed where there are familial or genetic disorders of the fetus that would lead to psychological affliction or undesirable

burden on the parents, or in the case of serious maternal disease. The aim of the legislation has been to decrease illegal and unsafe abortions. According to Dr Sadr, the head of the Legal Medicine Organization, this new act resulted in numerous requests for abortion due to disabling fetal disorders.²³ It should be mentioned that incidence of some congenital disorders such as haemoglobinopathies (particularly β -thalassaemia) is considerable due to the customary preference for consanguineous marriage. The proponents of the law emphasized the high cost and psychological trauma of children with birth defects.²³

Owing to ever-increasing attention on research ethics, the Specific National Ethical Guidelines for Biomedical Research were compiled in 2005²⁴ through a task force including experts in religion, law, ethics, medicine and related fields of science. Developed to observe ethical codes in research and to protect research participants' rights, ethical guidelines were developed for clinical trials, research on minors, genetic research, gamete and embryo research, transplantation research and research on animals. They are in accordance with the international frameworks. Similar acts and guidelines of other countries were used as references for compiling the draft. Completion and revision of the drafts was carried out in several stages of focus group discussion and specific panels by religious scholars, lawyers, ethics experts and medical practitioners under the supervision of the Medical Ethics and Medical History Research Centre of Tehran University of Medical Sciences. The final review was accomplished by the authorities of the Policy-making Council of MOHME in 2005. The guidelines are available through the website of the Medical Ethics and Medical History Research Centre (available at: <http://mehr.tums.ac.ir/Codes.aspx>) in Farsi. Furthermore, some have been translated and published in English language journals.^{25–27}

Within the specific section on clinical trials, some topics include: participants' rights and informed consent, placebo-controlled trials, ethical review committee's responsibilities and compensation. The section on genetic

research included ethics in prenatal diagnosis, confidentiality of genetic data, ethics in gene therapy and ethics in genetic consultation.²⁵ Currently there is no absolute restriction on genetic research in the Islamic Republic of Iran. However, moral principles and ethical codes must be followed completely. Prenatal diagnosis is permissible only if it is concerned with mother or fetus health and eugenic research is prohibited.²⁸ The guidelines for research on vulnerable groups focus mainly on: patients with mental disorders, children, pregnant women and neonates, prisoners and research in emergency situations.

In view of growing interests in the field of ART and stem cell research, the guidelines on gamete and embryo research included: ethics in ART, ethics in human gamete and embryo research, and ethics in research on the fetus.²⁵ The guideline mentions essential ethical principles which should be considered in research on embryos. The Islamic Republic of Iran is the 10th country in the world which has produced, cultured and frozen human embryonic stem cells. Iranian scientists have established human stem cell lines since 2004. According to religious decrees, human reproductive cloning is not permitted, even though Muslim shi'a religious leaders have issued decrees authorizing animal cloning. Moreover, stem cell research and cloning for therapeutic purposes is permissible with full consideration and all possible precautions only in "pre-ensoulment" stages of fetus development.²⁹

The guidelines for transplantation research address: using cadaver and living donors; issues related to the recipients; and using organs or tissues obtained from human embryo or fetus in transplantation research.²⁶ Finally, the guidelines for research on animals covers the main issues of provision and transportation of animals, protocols of care and use of animals, and staff and researchers' qualifications.²⁷

The guidelines were communicated to the universities and research centres after ratification by the policy-making council of the MOHME. The ethics committees are responsible for putting the guidelines into practice in

applicable research. The committee members became familiar with the guidelines through workshops and educational sessions held by universities and research centres.

Conclusion

Concerns about the ethical issues of modern biotechnology and innovative science have prompted attempts to adopt new policies and regulations worldwide. There have been efforts to enact uniform and comprehensive laws to protect against the potential harm or misuse of biomedical science. Several challenges in the field of bioethics in the Islamic Republic of Iran led to specific efforts by the authorities to address these problems. It should be borne in mind that bioethics in Islamic countries is inseparable from religious jurisprudence. New regulations and guidelines on bioethics were compiled and put into practice using the Islamic point of view as the basis. Establishing and strengthening nationwide bioethics networks in collaboration with religious scholars, physicians, philosophers, legal experts, sociologists and other interested intellectuals would be useful. Likewise, increasing interrelation of medicine, religion, ethics and law requires greater understanding and analysis of medical ethics issues and the provision of culturally-adapted solutions.

Along with continuing national activities, we suggest extending global networks of bioethics for strengthening communications within organizations at the regional and international level. Designing and establishing convenient collaborative educational courses at different levels (e.g. through distance learning) is also suggested. ■

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Résumé

Législation nationale sur la bioéthique et recommandations pour la recherche biomédicale en République islamique d'Iran

Les progrès rapides des sciences et des technologies biomédicales, qui ont révolutionné les services médicaux et les prestations de soins de santé dans différentes sociétés, s'accompagnent de difficultés éthiques inévitables. Il indubitable que ces innovations pourraient conduire à des désastres irréversibles si elles ne sont pas encadrées par des réglementations appropriées.

Des efforts substantiels ont été consentis en République islamique d'Iran pour tenter d'établir une approche structurée permettant d'identifier, d'analyser et de résoudre les questions éthiques posées par la pratique clinique. Compte tenu du

consensus atteint entre les spécialistes religieux et scientifiques, le parlement a récemment approuvé un certain nombre de lois, dont celle sur la transplantation d'organes provenant de patients décédés ou en état de mort cérébrale (2000), celle sur le don d'embryons aux épouses stériles (2003) et celle sur l'avortement thérapeutique (2005). Les autorités ont également élaboré des recommandations nationales concernant l'évaluation et la supervision éthiques des projets de recherche. Le présent article passe en revue les principaux efforts de la République islamique d'Iran pour légiférer dans le domaine bioéthique.

Resumen

Leyes y directrices nacionales de bioética para la investigación biomédica en la República Islámica del Irán

Los rápidos avances registrados en el terreno de la ciencia y la tecnología biomédicas, que han revolucionado la medicina y la atención sanitaria en diferentes sociedades, han traído consigo inevitablemente diversos retos éticos. No cabe duda de que esas innovaciones pueden provocar desastres irreversibles si no se limitan con las medidas regulatorias oportunas.

En la República Islámica del Irán se han dado pasos importantes para establecer un sistema estructurado que permita identificar, analizar y resolver los aspectos éticos de la práctica clínica. Gracias al consenso de expertos religiosos y científicos,

entre las leyes recientemente aprobadas por el parlamento figuran la Ley de trasplante de órganos de fallecidos y pacientes con muerte cerebral (2000), la Ley de donación de embriones para cónyuges infértiles (2003) y la Ley de aborto terapéutico (2005). Las autoridades han recopilado además directrices nacionales para la evaluación y supervisión ética de las propuestas de investigación. A lo largo del artículo se analizan las principales iniciativas emprendidas en materia de legislación bioética en la República Islámica del Irán.

ملخص

تشريعات الأخلاقيات البيولوجية الوطنية والدلائل الإرشادية للبحوث الطبية البيولوجية في جمهورية إيران الإسلامية

اقرها البرلمان مؤخراً تتضمن المرسوم (2000) الخاص بزراعة الأعضاء المأخوذة من المتوفين والمرضى المصابين بالموت الدماغى، والمرسوم (2003) الخاص بالتبرع بالأجنة للزوجة أو الزوج العقيم، والمرسوم (2005) الخاص بالإجهاض العلاجى. وقامت السلطات بتجميع الدلائل الإرشادية الوطنية الخاصة بالتقييم الأخلاقى، والإشراف على المقترحات البحثية. وتعرض هذه الورقة البحثية المساعي الأساسية المبذولة في مجال التشريعات الأخلاقية البيولوجية في جمهورية إيران الإسلامية.

إن التقدم السريع في مجال العلوم والتكنولوجيا الطبية الحيوية، والذي أحدث ثورة في الطب وخدمات الرعاية الصحية في مختلف المجتمعات، قد صاحبه تحديات أخلاقية حتمية. ولاريب في أن هذه الابتكارات قد تفضي إلى كوارث غير قابلة للإصلاح، ما لم تحكمها الأنظمة الملائمة. وقد أجريت محاولات كثيرة في جمهورية إيران الإسلامية لإيجاد أسلوب منظم لتحديد القضايا الأخلاقية في الممارسة الإكلينيكية (السريرية)، وإيجاد الحلول لها. وفي ضوء إجماع العلماء ورجال الدين، فإن بعض القوانين التي

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