



## Human embryonic stem cell science and policy: The case of Iran



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### ABSTRACT

The paper is based on a large qualitative study of ethics, policy and regulation of human embryonic stem cell (hESC) science in Iran. This case study in five academic research centres used semi-structured interviews to examine in depth the views of stem cell scientists, embryologists and ethics committee members on hESC research policy in this *Shia* Muslim country. Although Iran's policy approach has been considered 'intermediate', what is described here seems to be a 'more flexible' policy on hESC science. This article describes three arguments to explain why Iran has shaped such a policy. These are: (1) a flexibility of the *Shia* tradition has allowed for hESC science; (2) permissive policy related to other fields of biomedicine, such as new assisted reproductive technologies, facilitated approval of hESC research; and (3) a lack of public debate of bioscience in Iran influences how its hESC research policy is perceived. Based on the empirical data, this paper then expands and refines the conceptual bioethical basis for the co-production of science, policy, and society in Iran. The notion of co-production implies that scientists, policy-makers, and sometimes other societal actors cooperate in the exchange, production, and application of knowledge to make science policy.

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### Introduction

The increasing use of human embryonic stem cell (hESC) lines for research and therapy, as an innovation pathway, has stimulated controversy internationally about the procurement, use and disposal of the embryos. The debate over hESC research is mainly caused by the diversity of ethical and policy issues. Social science, the ethics literature and analysis of policy documents shape discourses, debates, and shifts in this area of bioscience (see, e.g., Franklin, 2005; Isasi & Knoppers, 2006; Parry, 2003; Wainwright, Williams, Michael, Farsides, & Cribb, 2006). Nations across the globe have demonstrated widely divergent levels of tolerance for allowing, funding and regulating hESC science. Taking a 'conservative' approach, some countries allow moral concerns to drive their policy. Other countries take a more 'progressive' approach with centralised regulated systems for hESC science (see Walters, 2004). While several developed countries like the UK, have taken the 'permissive' approach based on long-standing regulation (Isasi & Knoppers, 2006) or specific governance frameworks (Parry, 2006).

In developing countries, regulation of this field is a new challenge; responses range from severe restriction to nonspecific or even nonexistent frameworks (Harmon, 2008; Isasi & Knoppers, 2006).

In the Muslim Middle East, only Iran, Turkey and Tunisia have adopted a national policy on hESC science. According to the policy literature, Iran (Walters, 2004) and Turkey (Ozturk Turkmen & Arda, 2008) adopted an 'intermediate' policy that allow researchers to utilise existing hESC lines and use embryos created but not used for *in vitro* fertilisation (IVF). In contrast, Tunisia has banned acquisition of embryos for experimental purposes and allows them to be preserved only for therapeutic purposes, to help infertile couples (Tebourski & Ammar-Elgaaid, 2004).

In 2002 Iran's Supreme Leader, Ayatollah Khamenei, issued a 'stem cell *fatwa*' that declared that experimentation with human embryos was consistent with *Shia* tradition and congratulated the scientists who had produced hESC lines. (A *fatwa* is a religious opinion about whether or not an action is permissible.) Iran's clerics and political leaders have also actively promoted science and technology, in an attempt to enhance the country's international status. With the positive *fatwa* on the use of human embryos for stem cell (SC) research and therapeutic goals, Iran became the first Muslim country to produce, culture and freeze hESCs (see Baharvand et al., 2004). Rapid progress in SC science then led the Iranian government to put in place ethical and scientific supervision of this field of science. Compilation of the Specific National Ethical Guidelines for Biomedical Research (for instance, guidelines for genetic research and gamete and embryo research) has been a

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major effort in Iran in recent years (Larijani & Zahedi, 2008; Saniei & De Vries, 2008).

The purpose of this article is to briefly present the views of Iranian scientists, embryologists and ethics committee members about Iran's current hESC science policy and to examine some of the reasoning behind their perception. It sheds light on the attitudes of the participants noted above, who are relevant in understanding the status of this field and related policy, in Iran a *Shia* Muslim country.

## Method

Since little has been reported about the views of Iranian scientists and other actors on hESC science, ethics and policy, a case study design was chosen. The case study is an appropriate method when a researcher wants to study a subject in its natural setting and learn about the state of the art (Benbasat, Goldstein, & Mead, 1987). The major research project chosen to be studied integrates data from different sources using multiple methods, including field-work, internal archival research, and interviews with 30 senior and junior scientists, embryologists and ethics committee members (15 females and 15 males) associated with hESC science, from five academic SC research centres within Iran (The seniors interviewed can be considered elites in that they all occupy positions in power networks). To validate claims about the sites, an online search was conducted for other sources to see if the findings from interview data could be corroborated and to identify any contradictory evidence (e.g., about the ethical guidelines on hESC research).

Following approvals by ethics committee at King's College London and the Royan Institute in Iran, 'purposive' and 'snowball' sampling (Silverman, 2010) was done for maximum variation of ideas and perceptions, with the aim of recruiting enough numbers to reach thematic saturation. Interviewees were recruited using both formal and informal approaches and were given oral explanations and information sheets describing the research. Between March and May 2010 the interviews were conducted in Persian as guided conversations (Lofland & Lofland, 1984) lasting 55–170 min (average 95); an in-depth, semi-structured format allowed interviewees to use their own words and shape the discussion in ways related to their experience. None of the respondents objected to their interviews being quoted anonymously. Broad sets of questions covered interviewees' understanding of hESC science and policy and their general awareness of the contextual factors shaping the field.

All interviews were fully transcribed and then translated into English by the author, who is fluent in both languages, and a thematic approach was used to analyse the transcripts. The analysis and the themes that emerged were discussed with the author's supervisors and colleagues. This paper quotes from interviewees involved in science policy-making (12 interviews from 3 sites). It is important to note that though the quotes are typical of those interviewed for this study; they may not be generalisable to the wider scientific and academic community in Iran. To preserve anonymity, study numbers were assigned and reference to occupations is in general terms rather than by specific job titles. For instance, the category of 'scientist' could be used for those involved in producing the lines and for those who differentiate them into different kinds of cells.

## Results

### Themes

This analysis is organised into two major themes, each with several subthemes to help explain the overall findings of Iran's current policy on hESC science. Each theme corresponds to

embedded, inter-related ethical, social, legal and religious debates over Iran's hESC science policy.

### (Un)certain hESC science policy

Several different perceptions of hESC policy emerged in the interviews, in which some participants also expressed views that spanned more than one subtheme. Their comments mainly refer to Iran's current policy for hESC research, such as encouraging, more flexible, liberal and/or open-minded.

*Encouraging.* The first category is closely aligned with the official *fatwa* from Iran's Supreme Leader:

*They [the Iranian government] somehow encourage [scientists] to do this kind of [research]. This field, it seems, can respond to many human problems, related to [medical] disorders, war-damaged people, and many scientific questions. (Scientist/7/Male)*

Another interviewee added further details to this quote in explaining that:

*[Ethics policy] doesn't restrict our research activity. Our country fortunately emphasises the importance of improving research, discovering human creation, and helping patients. (Scientist/1/Male)*

Several interviewees said that it had been encouraging when Ayatollah Khamenei publicly supported the field in 2002. For the Supreme Leader, the main reason for doing hESC research was its 'global benefit' for human beings—he encouraged scientists to advance the technology to save lives, considering it a religious duty to carry out research in order to develop new medicines and technologies that can benefit humanity. Iran's goal should also be to become the 'leader of science' in the Middle East in the next 20 years (Khamenei, 2007). The scientific progress of Iranian science has been demonstrated by Rudolf Jaenisch's paper published in *Nature* (Jaenisch, 2007) as well as a stream of articles in *Science* and *Nature* about Iran's progress in science. Dr. Baharvand, the head of the Department of Stem Cell Research at the Royan Institute, stated: "[The] vision is to efficiently put stem cell research findings into operation in disease treatment to increase the level of health." (Morrison & Khademhosseini, 2006: 8). The task of scientists, then, is to promote scientific progress and keep Iran on the leading edge of discovery.

*More flexible.* With its 'permissive', 'flexible' and 'restrictive' policies on hESC research, Iran has adopted a 'flexible' policy, among the categories described by Hoffman (2008), though some other references named it as an 'intermediate' approach (see Isasi & Knoppers, 2006; Walters, 2004). Adhering to this policy, Iranian scientists would work only on 'spare' IVF embryos and they were not allowed to generate embryos for research purposes. However, a few interviewees considered the policy to be 'open-minded'. For instance, one ethics committee member noted that:

*We should go towards treating human by this method [hESC research and therapy] but we have to consider the ethical debates. This is our duty. There is no prohibition [on hESC research] in Iran and our policy is open-minded. Our research institutes are very active in hESC science to find the cure for debilitating diseases. (Theologian/Ethics Committee Member/30/Male)*

Several interviewees also drew attention to the use of the somatic cell nuclear transfer (SCNT) technique to provide SCs

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