# Policy, Equity and Priority: Ethical Issues of Stem Cell in Developing Countries

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#### Abstract

Ever-increasing advances in the field of bioethics have been encouraged by recent developments of biomedical technologies. Stem cell research and therapy are among the most promising approaches in medicine of which are raised some ethical challenges. Likewise, the therapeutic potential of stem cell-based therapies created new policy concerns for health care systems, particularly the issue of equity, priority in resource allocation and justice. There are arguments against and in favor of funding for stem cell research. Governments have also diverse policies in encouraging private sector sponsorship to support researches. Iran is one of the pioneers in the field of human embryonic stem cell research in the region. The religious decrees permitting therapeutic purposes have paved the way for wide-ranging researches. Indeed, the researchers have an obligation to observe moral values. Therefore, the national specific guideline for gamete and embryo research, compiled in 2005, is followed in this issue. In this paper, we will discuss the major ethical concerns relating to the issue of equity and justice, and will review the regulatory policies for stem cell research and therapy. On the whole, stem cell research is a global enterprise about which there is a need to think in the context of globalisation and also from the perspective of the developing countries. Stem cell based therapies are expensive and technologically demanding, the low-resource healthcare systems need to consider a specific national policy and to weigh up costs and benefits to consider making such treatments available. We must ensure that rights, values and welfare of the donor, recipient and the community are respected.

Keywords: Stem cell, Ethics, Policy, Equity, Developing country

### Introduction

The goal of medical ethics is to improve the quality of patient care by identifying, analysing, and attempting to resolve ethical problems that arise in the practice of clinical medicine (1, 2). Day by day, biomedical sciences offer new opportunities to improve human welfare; nevertheless, the ethical obligations set limits on how we use these abilities. The discovery of stem cells early in the 1980s had suggested therapeutic approaches to chronic, debilitating, and incurable diseases (3). Stem cells are "cells with the capacity for unlimited or prolonged self-renewal that can produce at least one type of highly differentiated descendant" (4). Stem cell research (SCR) currently is an important new field of biomedical advances with many promising therapeutic applications for a variety of devastating diseases including Parkinson's disease, multiple sclerosis and type 1 diabetes.

SC research, however, has aroused vigorous debate particularly about the source of the cells. Stem cells are derived through different ways (5). One source of stem cells is early embryos. This could be an IVF embryo remaining after infertility treatment, or this could be an embryo purposefully created for stem cell derivation. Stem cell could be also harvested from aborted foetuses, adult, or somatic stem cells; e.g., those harvested from umbilical cord blood. An alternative method of deriving human embryonic SC (hESC) is somatic cell nuclear transfer (SCNT), or cloning. Cloning and hESC research have been the subject of long-running debates within public and medical professions. There is no considerable controversy over the research on adult stem cells and cord blood, as other sources of stem cells.

Research on SC promises to yield new insights into the molecular control of cell differentiation

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(6). The clinical potential uses of stem cells are enormous, including neuronal repair, haematological reconstitution, and organ transplantation (7). Other applications for stem cells are also being investigated, for example as sources of differentiated cell types for drug screening and toxicity testing, or as vehicles for drug delivery (6). Research programs are underway using both embryonic stem cells (ESCs) and various types of non-embryonic stem cells. Most scientists agree that all types of stem cells should be studied to maximize the chances of developing successful therapies (6).

In spite of great advantages, stem cell therapy has potential complications and disadvantages that consist mainly of tumour formation, genetic abnormalities, infection, tissue rejection, immunological complications, failure rate and high cost.

We do discuss in this paper neither the raised opportunities by stem cell usage cells nor the wide-ranging ethical issues. In fact, this paper has two main aims; first, to present a review of the major ethical concerns related to the issue of equity and justice; and next, to provide an overview of regulatory policies for stem cell research and therapy. Stem cell research has created challenges for regulatory bodies, policy makers and scientists as they traverse their way through a tangled web of regulations and moral proselytizing (6). Currently, stem cell research is highly dynamic, with many questions and 'unknowns'. Scientific developments may actually remove some of the ethical concerns (8). In coming years, the national, regional, and international debate about ES research is likely to continue (9). We intend to draw necessary attention to some of the ethical challenges in the field of public policy which developing countries are facing.

## **Global Ethics and Stem Cell Research**

The ethical issues of stem cell can no longer be viewed only from perspective of developed countries. On the contrary, stem cell research currently is a global enterprise. Increasingly, aca-

demic collaborations cross national boundaries. Global bioethics seeks to identify key ethical problems faced by the world's six billion inhabitants and envisages solutions that transcend national borders and cultures (1). In this era that the International Association of Bioethics has been formed (10), and a wide-ranging discussion on global bioethics has been launched, all researchers from either developing or developed countries need to join the universal discourse. With increased knowledge, more developing countries have the opportunity to apply their efforts and ingenuity to benefit from new developments of health biotechnology (11). Scientists in both industrially advanced countries and developing countries can realize that many developing countries are active participants in this field. If developing countries are active innovators in new fields of science, there is an increased probability of appropriate health solutions for particular health needs of those countries. Organizations in developing countries are also likely to develop more affordable solutions to local health problems than organizations in richer nations (11).

It is noteworthy that in the age of global science, differences in moral values and cultural attitudes could have an impact on the practice of global science. As an illustration, such differences raise a dilemma when scientists have the option of importing material for stem cell research. The central question is whether it is ethical or legal to use imported material where the consent process meets the rules of the country of collection but not the standards of ethical sourcing that apply in the country of destination (6). Undoubtedly, religious backgrounds and socio-cultural traditions of different communities should be taken into account for ethical analysis of practice in such a situation.

## **Ethical Issues**

The special nature of human ES cells have arisen several issues in the review and oversight of research involving their use (12). SC research is morally controversial because it involves the deliberate production, use, and ultimate destruction of human embryos. The Moral status of human embryo is major ethical question in conducting this research. In order to derive hESCs, embryo must be destroyed at around 5-7 d after fertilization (the blastocyst stage) by harvesting cells from inner cell mass of embryo; the question is whether it is right to do this (6). Any society grappling with the questions of whether to allow embryo research, and under what conditions, must first resolve its stance on the issue of the moral status of the human embryo (6).

As noted, opponents of embryonic stem cell research are concerned with the moral and legal status of the embryo (13). Proponents, however, focus on the potential benefits to patients (14). They believe that there is an obligation to do everything possible to alleviate the suffering of existing human beings and, if ESC research has the potential to achieve that end, there is a moral duty to pursue it (6, 15). Some argue that there is a distinction between potential life and actual life; indeed, excess early embryos (less than 14 days old) are not yet human beings (16). Some argue "Instead of leaving the excess early embryos to perish, why not use them for research for the benefit of human beings?" Proponents, likewise, believe that "It is obligatory to pursue this research which has great potential to relieve human disease and suffering" (16). According to the majority of proponents, stem cells should be derived only from therapeutic cloning or from excess frozen embryos that were created for in vitro fertilization (16).

Further ethical debate surrounds the stem cell is the 'slippery slope' argument. It means that permission for therapeutic use of SC will make it more likely that reproductive purposes will eventually happen. But some believe that it is not logical to ban something, just because it can be misused; on the contrary, we should regulate and prevent misuse of technology and encourage research in the right direction (16). Given the great promise of ESC research for saving lives and alleviating suffering, it is reasonable to set the desired regulatory guidelines, and permit both the use of ESCs in research and the use of certain embryos to generate ESCs under necessary supervision.

Intellectual property in the field of SC research and new therapies, and the subject of patenting stem cell lines, called "patenting life" by religious objectors, are ongoing debates which have tenacious opponents. Some believe that broad patents and restrictive licenses may impede research. Another concern with the research use of human embryos focuses not on the moral status of the developing embryo, but on the harms to women who provide ova to create embryos destined to become stem cell sources. In addition to the physical harms, there are additional harms of coercion and economic exploitation (17). Certainly, those societies that decide to allow research on human embryos must ensure that the rights and values of the donors are respected (6).

There are also some ethical desiderata, from a public policy perspective, including cost-effectiveness, equitable access, and maximized potential therapeutic benefits across various demographic groups. It is too early to venture an economic evaluation of stem cell therapeutics, but stem cell tissues will surely be expensive (17). Consequently, the fair access of all members of the society to stem cell benefits might be an important issue in public policy.

In the current article, we continue by outlining the major arguments that have been put forward on the matter of equity and justice. We move on to review the current policy regulations on embryo research and therapy, including the situation of SC research in Iran, then highlight the religious issues raised by such research in different faiths.

### Policy, Justice, Equity, and Priority setting

SC research has accompanied with numerous ethical, economic, and organizational problems related to the issue of social justice and policy making. As stem cell technology progresses to the clinical setting, health care systems, especially publicly funded health care systems concerned with access, fairness, and cost control, will be challenged to derive, expand, and distribute cells and tissues routinely and on a massive scale (17).

One of the key ethical issues in the stem cell policy is proportionality. We need to weigh up the potential therapeutic benefits of the procedure of stem cell research and therapeutic cloning against its potential harms and disadvantages. On account of the fact that stem cell research could be an unrivalled approach to save many lives, it is difficult to argue that research into human ESCs is disproportional. On the other hand, the obligation to pursue the best medical treatment is a prima facie duty; therefore, it is not professionally acceptable for physicians to let millions of people die or continue to suffer from chronic and life-threatening diseases. Beyond that, we need to weigh out the costs and benefits. Despite their promise, stem cell based therapies are likely to remain, at least for many years, both expensive and technologically demanding (6). Although the claim that medical progress must be pursued at all costs is misguided (18), it would be wrong not to pursue cures which could be life-saving or could increase life expectancy and quality of life. Health organizations are required to set priorities and allocate resources within the constraint of limited funding (19). Priority setting is a challenge for every health care system in the world because demand for health care outweighs the supply of resources allocated to finance it (20). There are no widely accepted models for legitimate and fair priority setting in health care (20). Some have argued that to devise a rational priority setting system, cost effectiveness analysis is required. However, decision making based on the cost is in dispute.

There are justice and equity concerns relating to the financial cost of developing and purchasing such technology. Distributive justice (to allocate justly the medical resources, costs and benefits, among the community) is an important concern. Just distribution of potential benefits from stem cell research needs coherent well-structured planning. Equity, fairness and equality are the main factors in this issue. Justice, as the primary ethical consideration in health care resource allocation, would be considered at the national, provincial and municipal level (macroallocation), at the level of institutions (mesoallocation), or at the level of the individual patient (microallocation). At the level of meso- and microallocation, clinicians often find themselves in the role of manager, being required to set priorities, or affected by the decisions of others about priorities (1). Ethics, law, policy and empirical studies provide insights that can help clinicians as they try to distribute health care resources fairly (21).

At the level of macroallocation, policy makers are always faced with choices about how they should allocate or distribute scarce health resources and services, and what the most cost efficient ways of rationing those resources are. The fair policies need to be effective in alleviation of poverty and in closing the gap between different social classes in the societies. Respect to human dignity and rights should be the cornerstone of making decisions in the public policy.

There are different approaches for allocation of scarce resources; for instance some suggest distribution an equal share to each person, some recommend allocation according to need, merit, effort, contribution, and to free-market. Each of these has advocates and opponents. In the setting of health care, the most important recent advance has been the development of an ethics framework; accountability for reasonableness, for legitimate and fair decisions on setting priorities (1, 20, 22). Key elements of fair process will involve transparency about the grounds for decisions; appeals to rationales that all can accept as relevant to meet health needs fairly; and procedures for revising decisions in light of challenges to them (23). Together these elements assure "accountability for reasonableness" (22, 24). As mentioned, principles of justice are based on treating persons with fairness and equity and distributing the benefits and burdens of health care as fairly as possible in society. This would require equitable access to the benefits of stem cell research, without regard to the ability to pay (25). There will inevitably be opportunity costs for cash-limited healthcare systems considering making such treatments available. If healthcare services decide not to fund stem cell therapies, these therapies would be available only to individuals wealthy enough to pay for their own treatment. The issues of social justice and equity arise if the opportunity to live longer is available only to those who can afford access to an expensive treatment. It is suggested that a more rational approach would be to ensure 'commensurate work in ethics and social policy' to devise ways of coping with new challenges (6). Undoubtedly, rising public and professional expectations, an expanding pool of treatable patients and costly new technology must be balanced against tightly monitored health care budgets, competing government priorities and provincial deficits (21). What is required, and indeed what decision makers seem to be asked for, is a systematic, explicit approach to priority setting which is fair and, where possible, evidence based (19). Recent work, however, has suggested that decision makers within health organizations may require assistance for priority setting (26, 27). In addition, allocation of resources in health organizations tends to be conducted on the basis of historical or political patterns, which can lead to sub-optimal use of limited resources (28). In fact, it is clear that, at least in some jurisdictions, measuring the 'return on investment' and planning for how resources should be spent in the best way are not always very far advanced (29).

Other question of social justice may arise about tissue banks consisting of donated embryos or stem cells. An option for personalized stem cell lines would involve creating and banking personalized lines as insurance. Healthy individuals (as early as infancy) would bank personalized stem cell lines for the future possible use (17). Personalized stem cell lines for hematopoietic tissues could be created with cord blood drawn at birth, but for other tissues, the personalized cell lines would be derived from somatic cell nuclear transfer (SCNT) embryos created with the help of ova donors (17). The stem cell banks need to be controlled by health care providers. Different countries have to provide regulatory policies to ensure that the tissues are safe and ethically sourced.

It has been suggested that the stem cell bank should seek to build up a collection of clinicalgrade stem cell lines representing a range of different tissue types, with the aim of providing immunologically-matched lines for as many patients as possible. It is possible, however, that despite good intentions such repositories may fail to include the less common tissue types (30), such as potentially disadvantaging minority racial and ethnic groups (6). A just and equitable policy must also be sensitive to the needs of minorities who need social support to gain access to health resources.

On the subject of justice, some have mentioned the matter of intergenerational justice or equity. They believe that present decisions about health resources will have an impact on future generations. A just health care policy or program ought to have regard to considerations of efficiency in the sense that scarce health care resources should not be wasted.

Concerns have been expressed regarding the likelihood of accountability depending on whether ESC research is sponsored and/or conducted by the public or private sector. Some anticipate that in order for stem cell research to proceed most effectively, it will require an environment in which both public and private funding will be available (12). In fact, public and private research on human stem cells should be conducted in order to contribute to the rapidly advancing and changing scientific understanding of the potential of human stem cells from these various sources (25). Federal funding provides the opportunity for collaboration and coordination among a much larger group of researchers; moreover, it may lead to more widespread dissemination of findings and sharing of materials, which may enhance scientific discoveries (12). Federal funding for stem cell research is also necessary in order to promote investment in this promising line of research, to encourage sound public policy, and to foster public confidence in conducting such researches (25). On the other hand, federal regulatory and professional control mechanisms, combined with informed public dialogue, provide a sufficient framework for oversight of human stem cell research. Additionally, public funding contributes to sound social policy by increasing the probability that the results of stem cell research will reflect broad social priorities that are unlikely to be considered if the research is carried out in the private sector alone (25).

Government policies play a pivotal role in encouraging private sector involvement in this field. By encouraging collaborations and resource sharing among different institutions, many countries will be able to succeed in this field, despite their limited financial resources. Respect to intellectual property rights and patent legislation play an influential role for private sector involvement in this field, as in health biotechnology (31). It is important for businesses that invest large sums of money in stem cell research plus organizing a regulatory system which includes mechanisms for clear and secure chains of title, allows them to recoup investment through intellectual property rights, and to keep regulatory burdens minimal. Despite controversies, according to one report, patent activity has increased worldwide, with over 3,000 applications related to adult and embryonic stem cell fields of technology in the whole world since 2000 (6). Establishment of research ethics advisory boards should be encouraged in the private research centers.

According to some authorities, the new therapies could be safer, easier, and cheaper than some of the treatments governments are financing now. Nevertheless, these research projects should be ethically evaluated. It should be mentioned that in the hope of long- term payoff, some countries are increasingly investing in the arena of SC research and technology (9).

# **Regulatory Approaches**

Developing countries should seize the opportunity in order to build capacity in new technologies and to provide opportunities for developing in the field of health care and therapies for their populations. The governments of some developing countries started to pay special attention to SC research in recent years. They need to consider a national policy that will make best use of its resources (6). Developing countries can actively harness the potential of new technologies to improve the health of their peoples and thereby reduce global health inequities (31).

There are a range of regulatory approaches in different countries (5, 9). Six policy options regarding human embryonic stem cell (hESC) research have been adopted in the various nations and cultures of the world consisting of (9):

Option 1: No human embryo research is permitted, and no explicit permission is given to perform research on existing human embryonic stem cells;

Option 2: Research is permitted only on existing human embryonic stem cell lines, not on human embryonic (countries such as Austria, Ireland, Italy, Norway, and Poland);

Option 3: Research is permitted only on remaining embryos no longer needed for reproduction (e.g. The Czech Republic, Denmark, Finland, Greece, Hungary, the Netherlands, Russia, and Spain);

Option 4: Research is permitted both on remaining embryos and on embryos created specifically for research purposes through in vitro fertilization (IVF) (such as the United Kingdom, Belgium, Singapore);

Option 5: Research is permitted both on remaining embryos and on embryos created specifically for research purposes through somatic cell nuclear transfer into human eggs or zygotes (such as the United Kingdom, Belgium, Singapore);

Option 6: Research is permitted both on remaining embryos and on embryos created specifically for research purposes through the transfer of human somatic cell nuclei into nonhuman animal eggs, for example, rabbit eggs (for instance, China).

In Asia and the Pacific Rim, China has adopted the most liberal policies (32). It has permitted scientists to transfer human nuclei into animal eggs (Option 6). Stem cell research is also conducted in Iran, Egypt, Singapore, Saudi Arabia, and Malaysia. Iranian researchers succeeded to derive stem cells from human embryos in 2003 (9). Embryonic stem-cell lines are also produced in Singapore, and non-embryonic are derived in Saudi Arabia, and Malaysia (16).

Iran and the Organization of Islamic Conference also played a decisive role in blocking the U.S.-Vatican-Costa Rican attempt to have the U.N. adopt an international convention against research cloning (9). Muslim witnesses have testified in favour of the research and against restrictions on it; though, they argued against reproductive cloning.

Comparative legal research suggests that national policies reflect each country's historical experience, philosophical and religious traditions (6). In Iran, the rules, regulations, and practices regarding scientific issues such as SC research, about which there is no specific legislative act, are mainly based on the religious decrees (fatwas). Apart from human reproductive cloning, other kinds of stem cell research and cloning are permitted by most Iranian clergymen (33). As a result, in 2003 Iran became the tenth country in the world in production, culturing and freezing embryonic human stem cell lines. Furthermore, the cloned sheep, Royana, was born in Iran on September the 30<sup>th</sup>, 2006 (33). The Iranian Ministry of Health, and Medical Ethics and the History of Medicine Research Center (MEHRC) of Tehran University of Medical Sciences (TUMS) developed the "Specific National Ethical Guidelines for Biomedical Research", including the "Ethical Guidelines of Gamete and Embryo research" in 2005 (34). Although this guideline mentions essential ethical principles which should be considered in the researches on embryos, it needs to be brought up-to-date for the purposes of stem cell research and therapy. Special supervision is particularly important in order to ensure the guideline is being properly implemented in practice.

# **Religious Viewpoints**

One of the real illustrations of the influence of ideology on science is SC research. The religious faiths also have significant influences over the public-policy decisions.

As mentioned before, SC research is highly controversial because it involves deliberate production, use, and ultimate destruction of human embryos. The ontological status of the preimplantation embryo is the most sensitive point in this long-running dispute. Considerable differences of opinion exist with regard to the moral status of the pre-implantation embryo (35). On one side of the spectrum is the 'conceptionalist' view. According to this view the embryo is a 'person' and because of the potential of the embryo to develop into a person, it ought to be considered as a person. On the other side of the spectrum we find the view that the embryo (and even the fetus) as a 'non-person' ought not to be attributed any moral status at all (36).

Christians, Jewish, and Muslim scholars have adopted various positions regarding this novel type of research. Most theological perspectives consider the human fetus as an individualized human entity but there is substantial debate regarding the stage at which development of human dignity is conferred (conception, primitive streak development, implantation, ensoulment or birth) (35).

According to the dominant Catholic view, unborn is regarded as a human being from the time of conception (33). Because human embryonic stem cell research necessitates destruction of human embryos, such research is regarded as immoral by the Catholic Church, regardless of its possible benefits (37).

This view differs from the Jewish view based on which a fetus is not seen as being an ensouled person. Not only are the first forty days of conception considered 'like water' but also even in the last trimester, the fetus has a lesser moral status.

Some Islamic scholars hold favourable views toward embryonic stem-cell research from the perspective of sharia (Islamic law) (16). In Islam the embryo, even in the first day of its existence, has the right of life and we have any right to kill it. However there is a distinction between different stages of human development in uterus (35). Most of the scholars believe that ensoulment of the embryo occurs on the  $120^{th}$  day of the pregnancy, and that is the point when it gains its moral status or rights as a legal person. Some Islamic scholars, however, say ensoulment occurs on the  $40^{\text{th}}$  day (16). According to the dominant interpretation of the verses of the Holy Koran1, approved by both Shi'a and Sunni scholars, ensoulment takes place approximately four months after conception (38). Therefore, the use of embryo for therapeutic or research purposes may be acceptable under necessity if it takes place before the point at which the embryo is ensouled (35). Most Muslim religious authorities, moreover, do not consider cloning (at least therapeutic cloning) to be forbidden (39). In 2003, a scholar in Cairo issued a fatwa stating that therapeutic cloning of embryos would be considered lawful and could be compared to the accepted practice of donating cells, tissues, or organs for transplants (16). As noted before, Iranian scientists developed human embryonic stem-cell lines in 2003 with the approval of the supreme religious (Shiite) leader (16).

It is worth noticing that notwithstanding the acceptability of human ES research, the industrial creation of human embryos and their destruction in great numbers would be morally challenging in many jurisdictions (17). Human reproductive cloning is prohibited by many Muslim scholars mainly because it could be considered abuse of the woman who supplied the eggs or aborted the fetus, and because of a special concern that any human born from such an experiment would be more likely to suffer from impaired health and development. Furthermore, some Muslim scholars hold that the loss of kinship and lineage as a result of the unnaturalness of reproductive cloning, as well as potential social harms, are two major concerns about legalizing human cloning (38). Despite the existence of religious permission, most Muslim countries don't have laws concerning embryonic stem-cell research and cloning yet (16).

## Conclusion

The development of hESC lines represents an important advance in biomedicine that promises not only to expand basic scientific understanding but also to improve health and extend life for millions of patients (12). Stem cell therapy can potentially be applied to a wide spectrum of health problems all over the world. Some societies have attempted to produce legitimate decisions in this field. Regarding the clear benefits that can be derived from embryonic stem cell research, this research theme is a national priority in several countries such as UK and Australia (40). Developing countries, despite limited resources, should also find ways to use new technologies to meet local health needs. Fortunately, successful research is also taking place in several low income or developing countries. Despite the astonishing nature of stem cells and their potential to offer new therapies for some intractable diseases, deep-seated fears about ethical issues are aroused in many societies. In this paper we have emphasized the ethical issues of policy, equity and priority setting in SC research and therapy. The importance of these concerns will be realized when stem cell-derived therapies become a common practice in the not too distant future. Therefore, the importance of these issues should not be underesti-

<sup>1 . &</sup>quot;We created man of an extraction of clay, then we set him a drop in a safe lodging, then we created of the drop a clot, then we created of the clot a tissue, then we created of the tissue bones, then we covered the bones in flesh; thereafter we produced it an another creature. So blessed be God, the Best of Creators." (Holy Koran, Al-Muminun, Verses 12–14)

mated. Researchers' awareness and accountability is a crucial point.

The connection between ethics and public policy remains important. Special efforts should make to promote equitable access to the benefits of stem cell research (25). It is important to encourage the development of broadly beneficial therapeutic products with widespread access. More attention is needed to the ethics of protecting healthy people from undue risk, providing fair access, and sustaining the economic viability and equity of health systems as they accommodate new technologies (17). Maintaining public confidence is necessary for strengthening future research plans.

In addition to national appraisal and ongoing review, the regional and international oversight is absolutely needed. It is to be hoped, however, that the approach to policy development for stem cell research and therapy in the region will enable policy to evolve in a way that is rational and commands broad public support (6).

Taken all the noted points into account, setting standards of quality and safety and compiling appropriate ethical guidelines and directives for the process of donation, procurement, preservation, storage and distribution of hSCs are recommended. The opportunities that biomedical science offers to improve human welfare need to accompany with the limits set by important ethical obligations. An ethical public policy in our pluralistic world has to respect diverse fundamental beliefs among religious traditions. Besides, the regulatory frameworks are required to update in regular periods.

Finally, we recommend that research involving human embryos be permitted for therapeutic purposes with full considerations and all precautions. Establishing a comprehensive well-controlled system and appropriate ethical and scientific supervision of the widespread research programs should be pursued. It is beyond dispute that the field of stem cell therapy is still in its infancy; further ethical analysis is needed to guide policymaking in this field and to provide an appropriate evidence-based policy in developing countries.

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# References

- Singer PA (2000). Recent advances: Medical ethics. *BMJ*, 321:282-85. (doi:10.1136/bmj.321.7256.282)
- 2. Siegler M, Pellegrino ED, Singer PA (1990). Clinical medical ethics. J Clin Ethics, 1:5-9.
- 3. McHugh PR (2004). Zygote and Clonote-The Ethical Use of Embryonic Stem Cells. *New Eng J of Med*, 351(3):209-11.
- 4. Watt FM, Hogan BLM (2000). Out of Eden: stem cells and their niches. *Science*, 287: 1427-30.
- 5. Kneopffler N (2004). Stem Cell Research: An Ethics Evaluation of Policy Option. *Kennedy Inst Ethics J*, 14(1):55-74.
- Corrigan O, Liddell K, McMillan J, Stewart A, Wallace S (2006). Ethical, legal and social issues in stem cell research and therapy. A briefing paper from Cambridge Genetics Knowledge Park. Cambridge: Cambridge Genetics Knowledge Park, 2<sup>nd</sup> Edition. Available at: www.cgkp.org.uk
- 7. Vogel G (2000). Can old cells learn new tricks? Science, 287:1418.
- 8. Daar AS, Court BE, Singer PA (2004). Stem cell research and transplantation: science leading ethics. *Transplant Proc*, 36:2504-506.
- 9. Walters L (2004). Human embryonic cell research: an intercultural perspective. *Kennedy Inst Ethics J*, 14(1):3-38.
- 10. International Association of Bioethics. Available at:

http://bioethics-nternational.org/iab-2.0/index.php?show=index (accessed Sep 2007).

- Thorsteinsdóttir H, Quach U, Martin DK, Daar AS, Singer PA (2004). Introduction: promoting global health through biotechnology. *Nat Biotechnol*, 22(Suppl): DC3- DC7.
- National Bioethics Advisory Commission (1999). Ethical issues in human stem cell research. Volume I: Report and Recommendations of the National Bioethics Advisory Commission. Rockville, Maryland.
- 13. Young FE (2000). A time for restraint. Science, 287:1424.
- 14. Perry D (2000). Patients' voices: the powerful sound in the stem cell debate. Science, 287:1423.
- 15. Nuffield Council on Bioethics (2000). Stem cell therapy: the ethical issues. London: Nuffield Council on Bioethics. Available at: http://www.nuffieldbioethics.org/fileLib rary/doc/stem\_cell\_therapy2.doc (accessed Sep 2007).
- 16. Dabu CH (2005). Stem-cell science stirs debate in Muslim world, too. Christian Science Monitor, June 22. Available at: http://www.csmonitor.com/2005/0622/p1 5s02-wogi.html (accessed Sep 2007).
- 17. Giacomini M, Baylis F, Robert J (2007). Banking on it: Public policy and the ethics of stem cell research and development. *Soc Sci Med*, doi: 10.1016/j. socscimed. 2007.05.021
- 18. Coors ME (2002). Therapeutic cloning: from consequences to contradiction. *J Med Philos*, 27(3):297-317.
- Mitton C, Donaldson C (2004). Health care priority setting: principles practice and challenges. Biomed Central: Cost Effectiveness and Resource Allocation, 2: 3. Available at: http://www.resource-allocation.com/ content/2/1/3(accessed Sep 2007).
- 20. Gibson JL, Martin DK, Singer PA (2002). Priority setting for new technologies in

medicine: A transdisciplinary study. BMC Health Services Research, 2:14, doi: 10.1186/1472-6963-2-14. Available at: http://www.biomedcentral.com/1472-6963/2/14 (Accessed Sep 2007).

- McKneally MF, Dickens BM, Meslin EM, Singer PA (1997). Bioethics for clinicians: 13. *Resource allocation. Can Med Assoc J*, 157(2):163-67
- 22. Editorials (2000). Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles. *BMJ*, 321:1300-301.
- 23. Daniels N, Sabin J (1997). Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philos Public Aff*, 26:303-50.
- 24. Daniels N, Sabin J (1998). The ethics of accountability in managed care reform. Health Affairs, 17: 50-64.
- 25. Chapman AR, Frankel MS, Garfinkel MS (1999). Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research. Produced by the American Association for the Advancement of Science and *Institute for Civil Society*. November, p.1-39.
- 26. Lomas J, Woods J, Veenstra G (1997). Devolving authority for health care in Canada's provinces: 1. An introduction to the issues. *Can Med Assoc J*, 156(3):371-77.
- 27. Mitton C, Donaldson C (2002). Setting priorities in Canadian regional health authorities: a survey of key decision makers. Health Policy, 60(1):39-58.
- 28. Birch S, Chambers S (1993). To each according to need: a community-based approach to allocating health care resources. *Can Med Assoc J*, 149:607-12.
- 29. Donaldson C, Mitton C, Currie G (2002). Managing Medicare: the pre-requisite to spending or reform. The Health Papers No. 157. Toronto: CD Howe Institute.
- 30. Bok H, Schill K, Faden R (2004). Justice, ethnicity, and stem-cell banks. *Lancet*, 364(9429):118-21.

- Thorsteinsdóttir H, Quach U, Daar AS, Singer PA (2004). Conclusions: promoting biotechnology innovation in developing countries. *Nat Biotechnol*, 22(Suppl): DC48-52.
- 32. Anonymous (2004). Ethical Guideline Human Embryonic Stem Cell Research of the Ethics Committee of the Chinese National Human Genome Center at Shanghai. *Kennedy Inst Ethics J*, 14(1):47-54.
- 33. Aramesh K, Dabbagh S (2007). An Islamic View to Stem Cell Research and Cloning: Iran's Experience. *Am J Bioeth*, 7(2):62-3.
- 34. Medical Ethics and History of Medicine Research Center (MEHR) (2005). Guidelines for research on gamete and embryo [Farsi]. Available at: http://mehr.tums.ac.ir/code.asp (accessed December 10, 2006)
- 35. Larijani B, Zahedi F (2007). Cloning and Stem cell Research Issues: Religious Viewpoints on Value of Life. *Eubios Ethics Institute*, 17(3):70-1. (ABC8/BBRT2 abstracts).

- 36. deWert G, Mummery CH (2003). Human embryonic stem cells: research, ethics and policy. *Hum Reprod*, 18(4): 672-82.
- 37. Ohara N (2003). Ethical consideration of experimentation using living human embryo: The Catholic Church's position on human embryonic stem cell research and human cloning. *Clin Exp Obstet Gynecol*, 30(2-3):77-81.
- Larijani B, Zahedi F (2004). Islamic perspective on human cloning and stem cell research. *Transplant Proc*, 36(10):3188-89.
- 39. Sachedina A. Islamic perspectives on cloning. Available at: http://www.agora.forwomeninscience.co m/bioethics/2006/09/islamic\_perspectives \_on\_clonin.php (accessed on Sep 22, 2007).
- 40. Barratt CLR, St John JC, Afnan M (2004). Clinical challenges in providing embryos for stem cell initiatives. *Lancet*, 364(9429): 15-8.