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RESEARCH ARTICLE

Stem Cell Research in India: Socio-Ethical Concerns

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Abstract

The discovery of stem cells in the early 1980s and establishment of first hESC line in 1998 had suggested therapeutic approaches to chronic, debilitating and incurable diseases. This scientific triumph triggered an ethics and policy argument that persists even today.Bioethicists, religious pioneers, government authorities, patient groups, and researchers keep on debating whether this field of study represents a promise, a risk, or a blended moral picture for society

Most of the ethical debate surrounding stem cell research focus on the moral status of embryos and slippery slope argument. Besides this, stem cell research raises other important issues such as the issue of informed consent, donor's health risk, the commodification of body, etc. that have received relatively little attention in the public arena.

The transition in the focus of stem cell research from basic science to the development of therapies raises the important question of justice.Another question related to stem cell research is about the appropriate allocation of government and private resources in biomedicine and issue of proportionality. We have to weigh up the budding therapeutic benefits of stem cell research against its possible harms and disadvantages.

The current paper will discuss the major arguments on the matter of ethics, equity and justice in the stem cell research field and will review the current policy regulation related to stem cell research and therapy including the situation of stem cell research in India

1. Introduction:

Stem cell research is a critical new space for biomedical research, and it has tremendous therapeutic potential for debilitating diseases and injury. However, the path from bench to bedside is long and has proved ethical, social and legal minefield, and it involves many scientific, technological and social hurdles. As stem cell technology progresses from lab to clinics, raises the issues of morality, access, fairness, justice and cost control. This study tries to analyze those socio-ethical issues that have been coupled with the rise of stem cell technology in India.

Though many people are presently aware of the various health advantages stem cell research may deliver, they are less aware of the various ethical issues significant to the stem cell research. Most of the ethical debate, especially in the developed world, focuses on the morality of destroying human embryos for the benefit of others. However, in the developing countries, stem cell research raises other important ethical issues that have received relatively little attention in the public arena than the source of stem cell. The ethical issues of stem cell can no longer be viewed only from the perspective of developed countries. Stem cell research at present is a worldwide endeavor. There is expanding research collaborations across national

boundaries. Worldwide bioethics tries to distinguish key ethical issues confronted by the world's six billion peoples and predicts way out that go above national borders and cultures.

2. Literature Review:

Like many areas of biomedical science, stem cell research has provoked debate regarding ethics and regulation of the research and resulting therapies. Initially, these discussions focus mainly on the moral status of the embryo (*EuruStemCell, 2011)*. Apart from moral status of the embryo, broader ethical questions include the issue of informed consent, donor risk, affordability, accessibility, etc. *(Larijani and Zahedi, 2008; Dresser, 2010; Hermeren, 2012).*

Some studies have analyzed the complexities surrounding the proliferation of embryonic stem cell research and therapy, such as various social and cultural factors and linkages between IVF clinics and stem cell research *(Bharadwaj and Glasner, 2009; Glasner, 2009; Gupta,2011).* Most of these studies have focused on the development of embryonic stem cell therapy in India and associated ethical and governance concerns related to its proliferation. In contrast, only a few studies have studied the proliferation of therapies based on adult stem cells *(Patra and Sleeboom- Faulkner, 2010; Sleeboom-Faulkner and Patra, 2011).*

The study by Diane Beeson and Abby Lippman *(2006)* showed the short and long-term medical risks, exploitation of donor women and other ethical problems related to egg harvesting for stem cells. Faden et. al.(2003), Giacomini M, Baylis F, Robert J (2007) and Mark Mollar (2008) illustrated the problem of unequal biological access in stem cell research. They also argue for why there is an obligation to prevent these disparities in access from happening. McLeod and Baylis (2007) and Erica Haimes and Ken Taylor (2011) have raised the arguments related to the use of spare embryos from IVF clinics for stem cell research.

Previous studies have observed that India has no laws to oversee various stem cell activities, and that is why many clinicians are free to do whatever they want; they blame the incapacity of the DBT-ICMR guidelines for unregulated stem cell activities since these have no statutory power *(Bharadwaj and Glasner, 2009; Glasner, 2009; Patra and Sleeboom-Faulkner, 2009, 2010; Sleeboom-Faulkner and Patra, 2011; Salter, 2008).*

This paper tries to highlight the important socio-ethical issues raised by the clinical development and use of stem cells in India and what are the regulatory guidelines are here to deal with it. This will be of direct relevance to scientists, clinicians, companies, regulators and policymakers in both India and other countries.

3. Methodology:

The present paper is exploratory in nature. The study aims to analyze the various ethical, and social issues emerged with the proliferation of stem cell research and therapy in India. To carry out this study normative method has been used. Data collection for this study includes both primary and secondary sources. The primary source includes reports and government documents. The secondary source includes books, articles, journals, research papers, online sources, etc. For conducting this study, review of literature dealing with the ethical and social issues, particularly related to stem cell research has been carried out.

4. Scientific Background:

Stem cells are defined as cells that are capable of differentiating to give one or more types of mature bodily cells and of dividing to give further stem cells without loss of differentiation potential. They are undifferentiated, totipotent[1] and pluripotent[2] cells that generate or regenerate tissues *(Kumar et al., 2006)*.

[1] Totipotent cells have total potential, i.e., capacity to form an entire organism. Totipotency is the ability of a single cell to divide and produce all the differentiated cells in an organism, including extraembryonic membranes.

[2] Pluripotent means the potential of a cell to differentiate into any of the three germ layers: endoderm, mesoderm, or ectoderm. Pluripotent stem cells can give rise to any foetal or adult cell type. However, they

Stem cells can be classified into three categories on the basis of their source, i.e., embryonic, Adult, and cord blood cells. The embryonic stem cells are obtained from early embryos. This could be an IVF embryo remaining after infertility treatment or an embryo purposefully created for stem cell derivation. The embryonic stem cells are acquired from the inner mass of embryo at the blastocyst stage *(McLaren, 2007*). Stem cell could also be harvested from umbilical cord blood. An alternative method of obtaining human embryonic stem cell (hESC) is induced pluripotent stem cells (iPS cells).[3] Adult stem cells are with limited potency and can be derived from adult body organs, e.g. Bone marrow, adipose tissues, cardiac tissues, etc.

5. Socio-ethical issues:

Stem cells offer hope to understand basic biology and to treat various debilitating diseases and abnormal conditions of the human body such as diabetes, Cardiac problem, Spinal cord injury, Liver disease, Muscular dystrophy, Cerebral palsy, Osteoarthritis, Autism, etc. However, there are many scientific, social and ethical challenges before stem cells materialize such hopes in practice.

First and foremost ethical challenge any society face regarding stem cell research is the ethical problems related to embryo research. The central argument in human embryonic stem cell research (hESCR) revolves around the moral status of human life in its most primitive stage (*Cahill, 2000*). Stem cell research is morally controversial because it involves the deliberate production, use, and ultimate destruction of human embryos (*Larijani, 2008*). The question is whether it is correct to do this.

The controversy surrounds around the concept of respect for persons, and it is argued that a fetus should also be treated as a person similar to babies, children, and adults. However, others believe that embryos have either no particular moral status or they have an intermediate status: "they are not the moral equivalents of infants, nor are they simply clumps of cells like any other tissue sample that can be used and discarded at will."(*Corrigan et.al., 2006)*

Similarly, the use of 'spare embryos' for research is another matter of concern. The proponents of using embryos in stem cells research argue that there is nothing wrong with using those 'surplus embryos' that are not going to be implanted. The creation of an embryo is regarded as immoral as it treats the embryo as a commodity in comparison to IVF embryos. However, the use of IVF embryos is not acceptable to many people on various religious and moral grounds. Opponents use the Kantian argument that persons must be treated as ends rather than as means. This suggests that a person's life cannot be sacrificed to accomplish some greater good.

Related to this is the issue of rights and safety of donors of these embryos destined to become stem cell source. Certainly, the societies that permitted the embryonic research have to make sure that rights and values of the donor must be protected. The donor must have complete information about the fate of their donated embryos.

At the legal level, donor's right is protected by the requirement of informed consent. Donors must be given 'thorough and appropriate information, including that stem cell lines that will be derived from their donated embryo/ tissue may continue indefinitely and may be used in different research projects'. The donor must also be informed that all stem cell lines may be banked and shared with others. Embryonic tissues may also be genetically modified and may be developed into commercial products whose intellectual property rights will not be of the donor.(*Skene, 2010)*

However, there are more subtle social and psychological issues that must be considered. Good research practice entails that IVF clinics ask couples to designate in advance how they want their extra embryos to be managed. However, couples undergoing the physically and psychologically stressful process of infertility treatment may not be in the best environment to assess the implications of donating their embryos or gametes for research purposes carefully. There is a danger that, despite being told they are under no

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alone cannot develop into a foetal or adult animal because they lack the potential to contribute to extraembryonic tissue such as the placenta.

[3] Through transcriptional reprogramming, somatic cells such as fibroblasts can be converted into iPS cells that resemble embryonic stem cells.

obligation to consent, they may nevertheless feel under pressure to do so, or be overwhelmed by the extra burden that informed decision-making entails. *(Haimes et.al, 2011)*

In India problem of informed consent is further complicated by the fact that India is a multi-language country with numerous dialects. English consent form that's also in technical language, difficult to understand by most of the people. According to a doctor ". English informed consent; nobody can understand, because in India we sign papers without reading and it's the done thing . . . There's no Hindi equivalent or no other language equivalent, so the informed consent [is] a joke. …".(Glasner, 2009) Official consent forms, therefore, need to be translated into multiple languages and dialects, particularly in rural areas where literacy rates are very low.

Apart from philosophical debates about using embryos in research, there are apprehensions that embryos will be also used as a commodity similar to human organs and other tissues. In Science and Technology Studies (STS), various studies have shown the increasing linkages between biomedical advances and the market *(Sunder Rajan, 2006).* Donation of oocytes to help childless is generally considered as a philanthropic act. However, there has been contention over the question of whether women who give "extra" eggs made amid their IVF treatment ought to be compensated with rebates on the expense of their treatment.

It is also debatable whether the donation of oocytes for the creation of embryos for stem cell research ought to be considered as philanthropic, given the commercial profits that may eventually flow from this work. In any case, the matter of making payments for gametes remains morally disputable as many consider this to be promoting the 'Commodification of the body' and furthering the exploitation of women's bodies in particular. *(Corrigan et.al., 2006)*

The construction of embryos for research or therapy, either by fertilization of gametes or by cell nuclear replacement requires a supply of ovum. Ovum donation involves administration of hormones which leads to hyperstimulation of the ovaries, followed by surgery to collect the ovum. It, therefore, carries a remarkable medical risk to the donor, both in short and long term. The most immediate risk from ovarian stimulation is ovarian hyperstimulation syndrome (OHSS) whose symptoms are nausea, vomiting, diarrhoea, and abdominal distention, etc. which in the long term leads to thrombo embolism, renal failure, respiratory distress, and haemorrhage from ovarian rupture (*Beeson et.al., 2006*). Beyond direct risks to the women undergoing ovarian stimulation, this may also have possible effect on offsprings. Experiment on mice shows that ovarian stimulation treatment results into growth retardation, a delay in ossification (bone development) and an eight-fold increase in a significant rib deformity.(*Beeson et.al., 2006)*

There are some socio- ethical consideration from public policy perspective also, such as affordability, equitable access, justice and appropriate allocation of limited resources, etc. It is too early to venture an economic evaluation of stem cell therapeutics, but stem cell tissues will surely be expensive. Even though basic science studies involving stem cells may offer scientists some assistance in developing new treatments and other relatively affordable medical interventions, the stem cell therapies that regenerative medicine supporters portray could be relatively expensive. As one group considering justice questions raised by stem cell research observed, "It appears expected, and genuine moral concern, that there will be significant economic barriers to access to new therapies utilizing stem cells based preparations" (*Dresser, 2010*). If stem cell research produces expensive treatments then how many people will be able to benefit from the research investment? Therefore, the fair access of all members of the society to stem cell benefits might be an important issue in public policy.

Stem cell research raises questions about the appropriate allocation of government and private resources in biomedicine. Stem cell research very well demonstrates the correlation between research financing decisions and social justice contemplation. Stem cell research is only one form of promising research. The government is the largest funding agency of biomedical science, supports many kinds of research offering opportunities to advance knowledge. The research portfolios of industry and nonprofit organizations likewise uncover a variety of promising research areas. However, neither the public nor the private sector can bolster every encouraging research plan. Every research funding source has limited resources. As a result, these entities face hard choices about where to invest their limited resources. The choices these entities make about research funding allocation raise social justice issues. Public funding agencies have a duty to distribute its resources in a just manner.

The social justice inquest is significant to various fields of biomedical inquiry, not only stem cell research. Certainly, such an inquiry may bolster research on some conditions that are the emphasis on stem cell research, for example, juvenile diabetes and spinal cord injury, which affect large young populations. Nevertheless, it is crucial to consider stem cell research as just one of many scientific prospects that may bring health benefits. Financing in stem cell research will reduce the resources available for other kinds of biomedical research. In stem cell research, as in other research areas, the relative value and likely cost of any potential therapeutic benefits should be part of the decision-making about research priorities.(*Larijani et.al., 2008*)

The second matter of social justice concerns the relative importance of research needs and health care needs. Is it more essential to conduct research intended at improving care for future patients, or to provide better health care to today's patients? Is it moral to dedicate a huge amount of fund to research while such a large number of individuals need access to health care that may possibly provide them longer and healthier lives?

What legitimizes our country's generous interest in biomedical development, when a large number of individuals are denied access to proven medical interventions? All over again, the stem cell debate opens a window to a bigger ethical issue. The social justice inquiry brings up issues about the need that stem cell and other fundamental science studies ought to have in the competition for limited resources.

Despite various underlying issues highlighted above, in many countries stem cells are being frequently used in research and clinical settings. However, a few countries have banned the research using human embryos and its therapeutic applications given that it is considered as an immature therapy, except bone marrow adult stem cell transplantations. In India, along with bone marrow stem cell transplantations, embryonic stem cell, adult stem cells i.e. neural stem cell, cardiac stem cells, liver stem cells, etc. are being used in the treatment of various diseases. Patients both domestic and internationally are flocking to India in the hope of curing their disease. Stem cell-based treatment is considered as a moneymaking endeavor rather than an effort to help patients.

Despite great future advantages, stem cell therapy has potential complication and disadvantages such as tumor formation, infection, genetic abnormalities, immune rejection; failure rate, etc. Proportionality is the major issue in stem cell policy. We have to weigh up the potential therapeutic benefit of stem cell research against its potential harm and disadvantages.

6. Regulation:

The Indian council of medical research, Department of Health Research and Department of Biotechnology has laid down the 'ICMR-DBT Guidelines for Stem Cell Research' in 2007 and revised in 2012 to make sure that research with human stem cells is led in an accountable and ethically sensitive way and conforms to every regulatory nuts and bolts related to biomedical research generally and stem cell research specifically. According to these guidelines, any research on human subjects, including human embryos and fetuses should confirm protection of human dignity, human rights, and fundamental freedoms. (*Guidelines for stem cell research, 2012)*

All studies involving fetal tissue for research or therapy are permissible subject to approval by Institutional committee for stem cell research (IC-SCR) and institutional ethics committee (IEC). The IC-SCRT/IEC should assess the procedure of acquisition of gametes, blastocysts, or somatic cells with the goal of creating new hES cell lines, including procurement of blastocysts more than clinical need from infertility clinics. Guideline clearly says that 'consent for donation of surplus embryos should be acquired from every donor no less than 24 hours prior and not at the stage of donation itself. Even individuals who have given an earlier sign of their intention to donate embryos that remain unutilized after clinical consideration have to give fresh informed consent at the time of donation of the embryo for the creation of hES cell line. Donors ought to be informed that they retain the right to withdraw consent until the blastocysts are actually used in cell line derivation' *(Guidelines for stem cell research, 2012*). The donor likewise should know that cell lines may be created from the provided tissue, which may be banked and shared with others. They may likewise go through genetic manipulation, and have the potential for development of commercial products. In the later case, the intellectual property rights will not be of the donor.

According to guidelines, apart from bone marrow transplant, all other stem cell treatments should be considered as experimental. It ought to be conducted just as a clinical trial only after approval of the IC-SCR/IEC and DCGI (for marketable products). Every clinical trial should be registered with the NAC-SCR. There should be no Commodification of human oocyte, human sperm or human embryo by way of payment or services. Although, Women who undergo hormonal stimulation to generate oocytes specially for research purposes (such as for SCNT) may be compensated for direct expenditures incurred as a result of the procedure, as directed by the IC-SCR/ IEC. They have to be informed about potential hazards, complications, etc. which are related to the hormonal induction process.

However, it is observed that India has no laws to oversee various stem cell activities and that is why many clinicians are free to do whatever they want; they blame the incapacity of the DBT-ICMR guidelines for unregulated stem cell activities since these have no statutory power.

7. Findings:

1. The debate over stem cell research often takes the moral status of the embryo as the only decisive ethical issue.
2. Although, use of spare embryos from IVF clinics is allowed in many societies, it is not acceptable to many people on various religious and moral grounds.
3. The process of informed consent is often de-contextualized from practice, resulting in a ritualized formality. It appears that it is neither well established nor closely followed.
4. The issue of making payments for gametes remains ethically controversial as many see this as leading to the 'Commodification of the body' and furthering the exploitation of women's bodies.
5. The focus of stem cell research is more on 'elite' disease rather than 'poor' disease. In this way, it serves only the interests of the dominant class of society.
6. In India, stem cell activities are largely unregulated and this is because of the absence of strict laws.

8. Conclusion:

The debate over stem cell research offers an opportunity to examine a variety of ethical and social issues raised by biomedical innovation. The debates related to stem cell therapy have evolved from the controversies on human embryonic stem cells to the concerns about the social issues resulting from the clinical use of stem cells. Despite the great therapeutic potential of stem cells for some dreaded diseases, deep-rooted fears about ethical issues are aroused in many societies. This paper, apart from ethical issues related to use of embryos for research purpose, has emphasized on the issue of informed consent, donor's right and safety, affordability, accessibility and priority setting in resource allocation. The importance of these issues could not be undermined as it will be realized when stem cell-derived therapies become a common practice in the not too distant future. It is important to encourage the development of broadly beneficial therapeutic products with widespread access. More consideration is required to the ethics of protecting people from undue risk, providing fair access, and sustaining the financial viability and equity of health systems as they accommodate new technologies.

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