### **Review Research Paper**

# **Embryonic Stem Cell Research Ethical and Legal Controversies**

<sup>1</sup>Amit M Patil

#### **Abstract**

The discovery of stem cells particularly embryonic stem cells with its possible clinical application has generated great curiosity amongst medical professionals and general public. Embryonic stem cell research has become a challenging issue for biomedical scientists, policy makers and regulatory bodies.

The key controversial issue is the determination of moral and legal status of the embryo as embryo stem cell research involves retrieving embryonic tissue from spare embryos leading to their destruction. This embryo that has the full capacity to develop into a human being is sacrificed for the benefit of others. Global regulations monitoring stem cell research are also troubled with similar ethical and moral issues associated with it. The main source of embryonic tissue is the spare or supernumerary embryos created during infertility treatment by artificial reproductive techniques (ART). Sadly, in absence of regulatory provisions to govern them, the field of ART is open for all forms of medical malpraxis bearing direct implications on embryonic stem cell research. This article is an attempt to seek clarity on the concept of embryonic stem cell research and contentious issues associated with it.

**Key Words:** Stem cells, embryonic stem cell research, Moral and legal status of embryo, ART, Global regulation

#### Introduction:

Stem cell research has offered a new viable therapeutic option for debilitating diseases, injuries and other diseased conditions. The scope of stem cell based treatment has expanded in recent years due to advances in stem cell research and technologies. Now, stem cell based treatments have been established as standard clinical care in certain disorders like use of hematopoietic stem cells in leukemia's or use of limbal stem cells in corneal disorder.

Stem cell technology is speedily increasing within the field of regenerative medicine, granting DE novo production of functional tissue and providing for brand new diagnostic and therapeutic capabilities that will surpass the risk benefit ratio of typical existing reparative treatment modalities e.g. organ transplantation, rejuvenation of tissues. [1] The hype created by this discovery and so claimed by many research scientists has made people believe that something significant is happening.

#### **Corresponding Author:**

<sup>1</sup>Associate Professor, Department of Forensic Medicine & Toxicology, Padmashree Dr. D.Y. Patil Medical College, Hospital & Research Centre, Navi Mumbai 400706 Maharashtra India

E- mail: dramp1976@gmail.com DOR: 03.02.2014 DOA: 28.05.2014 Whatever promising future clinical application it holds, stem cell research especially embryonic stem cell research is associated with ethical, social and legal controversies.

What is so unethical about embryonic stem cell research? The major conflicting unethical issue identified with this research is extraction of embryonic stem cells by embryo destruction. The very embryo which has the capacity to become a human being is destroyed at the onset of its potentiality of becoming one of us. The current view about any clinical research is to look it from the view point of cardinal research principles of autonomy, justice, non-malfeasance and human dignity.

Any research which stands to violate these principles is bound to suffer from moral and ethical controversies. A research that involves embryo destruction will find it difficult to accommodate itself within these cardinal principles.

### Definition and Platforms of Stem cells:

Stem cells are one of the human body's master cells with the ability to grow into any one of the body's more than 200 cell types. [2] They are unspecialized and undifferentiated cells capable of self proliferation, migration and differentiation. The distinct characteristic associated with the stem cell is their potential of

self renewal and capacity to differentiate into specialized cell. In short they are immature precursor cells with a capacity to specialize and differentiate into a mature specialized cell.

- i. Embryonic Stem cells (ESCs): These are the first differentiation after fertilization of cells of the embryo proper. They are derived from the inner cell mass of the blastocyst, 4–5 days after fertilization. They are not totipotent, but pluripotent and capable of forming all other cells of the body.
- ii. Adult Stem Cells: These are derived from bone marrow, peripheral blood, tissues, muscles, adipose tissues, cartilage etc.

The adult stem cells are broadly classified as hematopoietic, non-hematopoietic and organ specific stem cells.

Hematopoietic stem cells are blood forming cells derived from bone marrow. Non-hematopoietic stem cells are mesenchymal stem cells (MSCs) present in many tissues like bone marrow, blood, cartilage, fat, placenta, liver etc.

MSCs have unique characteristics of differentiating into several cell lineages such as cartilage, bone etc. They are pluripotent, non immunogenic, not patient specific and have tendency to migrate to the sites of inflammation.

ii. Umbilical Cord Blood Stem Cells and Placental Stem Cells: Stem cells can also be isolated from the umbilical cord blood and placenta. Cord blood is found to be rich source of stem cells. They are multi potent in nature.

Further based on their capacity to divide and differentiate they may be totipotent, pluripotent or Multipotent. Totipotent stem cells give rise to all different types of stem cells in the body including a living organism e.g. fertilized egg. Pluripotent stem cells give rise to any type of cell except those required to form a foetus. Multipotent stem cell gives rise to specific different type of cells.

#### **Induced Pluripotent Stem Cell (IPSC):**

These are adult cells that are engineered or reprogrammed to become pluripotent i.e., to behave like an embryonic stem cell. The scientific experience with induced pluripotent stem cells till date seems to be very promising. Yamanaka and then Thomson have discovered ways to reprogram somatic cells to a primordial state and then redifferentiate them to tissues of choice. [3]

It is important to note that though IPSC technology as enormous potential, it is still at its infancy, and certainly does not do away with the need for ESCs. [4]

### Somatic Cell Nuclear Transplant (SCNT) – Cloning:

Known as cloning, SCNT was first demonstrated in 1997 through the creation of Dolly the sheep. [5] As it suggest, it is simply the transfer of a somatic cell nucleus into an enucleated oocyte that can give rise to a cloned zygote from which embryonic stem cells can ultimately be derived. [6]

### Human Embryonic Stem Cells (HESCs) Sources:

HESCs are derived from the inner cell mass of the human blastocysts. Blastocyst is formed five days after fertilization of the egg by the sperm. It has outer shell which matures and if survives implantation becomes placental tissue and the inner cell mass becomes the tissues of the human body.

The extraction of HESCs from inner cell mass for research purpose leads to the destruction of the embryo. The major source of human embryonic stem cell tissues are the spare or supernumerary embryos created during in vitro fertilization as a part of infertility treatment. The other source is creating embryos with somatic cell nuclear transfer techniques (SCNT). The legislation of most countries including India allows use of spare or supernumerary embryos either fresh or frozen created during in-vitro fertilization.

Some countries with more liberal view have allowed creation of human embryos with SCNT as a source of embryonic tissues. The controversial issue in embryo research is concerned with which embryos are suitable and can be used for research.

There is disagreement over whether it is appropriate to create embryos solely for research purposes, and what techniques should be used to create those embryos. Many people and governments feel that an appropriate restriction on embryo research is to limit the use of embryos in research to those embryos that are surplus to infertility treatments. [7]

### The Status of the Embryo- Moral, Legal, Personhood:

As mentioned earlier, the extraction of embryonic tissue for research purpose involves destruction of the embryo. So what is wrong with destroying embryo? Most of these arguments about the rightness and wrongness of embryo destruction are based on the moral status of the embryo. The moral wrongness associated with embryo destruction will not only make the research impermissible but also deny the potential benefits expected from this research.

The use of human embryonic tissues for research poses a moral problem as it brings two highly valued but conflicting moral principles: the inherent duty to provide treatment to ease pain and suffering on one hand and the value of human life and dignity on the other.

Extraction of stem cells from human embryos violates the second principle as it leads to destruction of potential human life. Both principles cannot coexist together, but which principle takes precedence is a rather contentious issue. How the embryo should be considered from moral or legal point of view is the main debatable issue associated with HESC research.

### Deciding the Moral Status of the Embryo:

It's very difficult to ascertain the moral status of the embryo as it varies. There are different views about this moral status. The leading views deliberate that the embryo has the status of Persons, or Potential persons, or Divine creations, or Subjects of moral harm, or the beginning of human life with intrinsic value, or organic material with no moral standing than other body parts. [8] The development of human life or person is an evolving process starting from fertilization to the birth of a new born.

The early stages of development mostly compromise of cellular differentiation whereas at the end, the foetus assumes its full form both in physical and functional status.

There is no clear cut demarcation during this process of physical development as to when personhood is acquired. At one end of the spectrum of views on this issue is the belief that the embryo, from the moment of conception, is created by God and is a person in its own right with the same moral status as an adult human.

Those who hold this view, such as Catholic Bishop Richard Doerflinger, say that it is wrong to destroy embryos of any gestational age, for any purpose. [9] This absolutist view is not shared by all those with religious beliefs.

A substitute stance is that the embryo acquires full personal identity, and the ethical rights that come with this status, step by step during the process of development occurring between conception and birth.

It is so ethically acceptable, under these circumstances, to use embryo for research purpose. This read has been defended by some theologians of alternative faiths, together with Protestant, Christians, Jews, Muslims and Buddhists, and is additionally seconded by many folks who don't have a religious faith. [10]

The embryo in its early stage is a cellular structure and don't have the psychological, physiological, emotional and intellectual characteristics that we tend to attribute with individuality. [11]

It, therefore, follows that if human embryo does not fulfill the criteria for personhood; it does not have any interests to be protected and thus may be instrumentally used for the benefit of other human persons. [12]

In the discussion about embryo research, the formation of the primitive streak is considered as an important landmark point. The primitive streak, seen in the form of appearance of a surface thickening, is the first visible organization of the embryo which usually happens around fourteen days after fertilization.

The term 'pre-embryo' was introduced in 1985 to describe the early embryo up to this point. One argument that was used to justify drawing a distinction between the pre-embryo and the embryo proper was that the possibility of splitting the pre-embryo into two parts or twin parts. It appears, as per this argument, that the pre-embryo wasn't 'a person', as personhood is commonly taken to imply indivisibility or individuality. [13]

Others have argued that the concept of the pre-embryo is a rhetorical device invented to justify embryo research and that it creates an artificial division in what is, in reality, a continuous biological process of development. [14,15] Some research workers argue that the formation of central nervous system should be considered as the landmark for the definition of life, since this implies that the possibility of sensation initially exists.

Up to 14 days of embryonic period, the blastocyst has no central nervous system and therefore, cannot be considered as sensate. If we can remove organs from brain dead declared patients who are alive in some sense, then we can use two hundred-cell embryos as cell donors at the same moral status as brain dead individuals. [16]

It is argued that the early stage embryo is not sufficiently personalized to posses the ethical and moral weightage of personhood. [17]

There is another viewpoint of the "relative value" of human embryos, more than cells but less than persons. [18] This view states that embryos deserve respect but not to the same extent as a fully developed person.

In accordance with this argument, the moral status of a human embryo increases in a step wise manner through its development in the uterus, and at the point of birth it is entitled to enjoy full rights of human beings. [19] From the

entire deliberations one can conclude that the human embryo deserves respect but it cannot be considered as a person as it lacks the essential attributes of personhood.

### Legal and Constitutional Status of the Embryo/Unborn Foetus:

The Universal Declaration of Human Rights (UDHR) in its Article 1 says that: "All human beings are born free and equal in dignity and rights". [20] "The word "born was used to exclude the foetus and embryo from granting human rights. An amendment was proposed and rejected that would have deleted the word "born", as it was deliberated to protect the right to life from the moment of conception." [21]

Even the Convention on the Rights of the Child does not recognize the right to life until birth. [21] Thus a foetus has no rights under UDHR. The main standard for the protection of human life in general international law is Article 6 of the Covenant on Civil and Political Rights (CCPR). Article 6 of the CCPR, in its first paragraph the norm prescribes that "every human being has the inherent right to life. However, the phraseology of the norm doesn't outline the term "human being". [22] The unborn foetus has full potential to become a human being in right environment.

The liberal interpretation of the above fundamental right, one can conclude that the unborn foetus, from the conception till birth, has a right of life and it is immaterial whether the foetus is created in vitro or in vivo. Now, if this standard were transferred to all forms of unborn life, not only would research with embryonic stem cells infringe upon Art. 6 CCPR, but the legality of liberal abortion laws would also be highly debatable. [22]

The US Supreme Court has never ruled on the constitutional status of embryos outside of the body and most US states have no law on the matter. But the court has ruled that foetuses are not persons within the meaning of the 14<sup>th</sup> Amendment, and thus do not have constitutional rights as such. Presumably that ruling would also extend to embryos as well. [23]

Article 4 of the American Convention on Human Rights states: "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life". [24]

But the Inter-American Commission on Human Rights, one of two adjudicatory bodies that interprets and monitors compliance with the American Convention, has clarified that this protection is not absolute." [25] Article 2(1) of the European Convention on Human Rights provides: "Everyone's right to life shall be protected by law." [26]

The European Commission on Human Rights, in Paton v. United Kingdom, held that the Convention language "tend[s] to support the view that [Article 2] does not include the unborn," and acknowledged that recognition of an absolute right to life before birth would "be contrary to the object and purpose of the Convention." [25]

In Vo v. France, the European Court of Human Rights, which interprets and monitors compliance with the European Convention, affirmed that "the unborn child is not regarded as a 'person' directly protected by Article 2 of the Convention and that if the unborn do have a 'right' to 'life,' it is implicitly limited by the mother's rights and interests, including her rights to life, health, and privacy." [25]

The above judgement brings forth another controversial issue of foetal rights versus maternal rights of autonomy. The liberalized abortion laws existing in different countries and so proposed by various organizations have clearly determined the precedence of maternal rights over foetal rights.

The basic fundamental right to life is guaranteed by Article 21 of the Constitution of India. It says that no person shall be deprived of his life or personal liberty except according to procedure established by law. Even here the term "person" is not defined.

The Indian Legal System provides for the protection of the rights of the foetus through sections 312 to 316 of the Indian Penal Code (IPC) which deals with miscarriage. [27]

Section 315 IPC deals with "Act done with intent to prevent child being born alive or to cause it to die after birth" and Section 316 IPC deals with "Causing death of a quick unborn child by act amounting to culpable homicide. In the above penal provisions, the unborn child is protected from any act which prevents it from being born and also provides punishment for causing its death which is considered equivalent to culpable homicide.

Section 416 of Code of Criminal Procedure (CrPC) Act 1973 provides for postponement of capital sentence of pregnant women and also to commutes the sentence to life imprisonment in such circumstances. [27]

This provision is made to protect the life of unborn foetus as it has nothing to do with the act committed by the pregnant woman. Here the legislation has considered the unborn foetus as a distinct and separate individual/entity with the right of protection against potential harm.

The Section 13 of the Transfer of Property Act, 1882 deals with the transfer of property for the benefit of unborn.

Here the statue has defined the unborn as legal person by fiction. From the above legal provisions it is clear that the unborn foetus is protected against potential harm in the same manner as the fundamental rights of non interference with personal life and bodily integrity guaranteed to a human person.

If embryo is granted the status of personhood then they too will have the right of not to be harmed or killed with imposed obligations of not to do so.

The lack of clarity on the status of the embryo and deliberations put forth by constitutions of various countries and decision given by competent courts it can be assumed that the foetuses are not a person and hence cannot enjoy fundamental constitutional rights meant for human beings or persons.

Though the IPC and CrPC provide protection to the foetus from potential harm the Indian Constitution is silent on this aspect of extending the fundamental rights to the unborn foetus in clear terms.

### Value of Embryos:

The spare embryos which are the outcome of infertility treatment are the essential source of embryonic tissue. These embryos can either be used for embryonic stem cell research or can be discarded as leftover material once the objective of infertility treatment is achieved.

In other words, should we consider them as waste material or treat them as valuable commodity. "For donor couples, the transformation of embryos from intended babies, to 'waste' or 'leftover' material and then finally a source of precious stem cells is a complex and value laden process." [28]

The transformation of discarded embryos into stem cells has been referred to by one scientist as the process of turning 'garbage into gold'. [29] The child intending couples have to make emotional, physical and financial investment to reap the benefits in terms of successful pregnancy though this beneficial outcome cannot be always guaranteed.

The so considered 'waste materials' has economic value considering the initial substantive financial and emotional/physical cost incurred by these donors.

Also the potential commercial value associated with the result of embryonic stem cell research using such embryos might be tremendous. Pharmaceutical and Biotech companies will earn substantive commercial profit that may eventually flow from this work.

This raises an important question about the right of the donor couple to seek or claim financial stake or compensation. Nevertheless it is illegal under the Human Fertilization and Embryo Act (HFEA) of the United Kingdom (UK) for them to incur any financial reward for donating their embryos and they have no financial stake in any materials or procedures developed from their donation. [13]

Most commentators support a ban on the 'sale of embryos. For example, the European Group on Ethics in Science and New Technologies has stated that 'embryos as well as cadaveric tissues and foetal tissues must not be bought or sold....Measures should be taken to prevent such commercialization.

It is illegal for gametes to be bought or sold. An increasing number of biotech and pharmaceutical companies are gathering an array of 'valuable' bodily materials including DNA samples and umbilical cord blood (also used for stem cell research) from various corners of the globe for scientific and commercial exploitation. [13]

However, the issue of making payments to gamete donors or embryo donors remains ethically controversial as it may lead to "commodification of the body".

## Global Legislation Governing Embryonic Stem Cell Research:

Legislation governing human embryonic stem cell research is not uniform and varies from country to country. [30,31] Most of them have allowed use of spare or supernumerary embryos created during in-vitro fertilization for this purpose but have prohibited creation of human embryos specifically for research purposes.

The use of spare or excess embryos is subjected to certain provisions like informed consent, donation of embryos without financial compensation and restrictions on the use of embryo not beyond fourteen days.

Few countries have put prohibitions on buying and selling of gametes, fertilized eggs, embryos and foetal tissues.

But some countries with more liberal view have allowed creation of human embryos for research purpose with somatic cell nuclear transfer technique as well as use of supernumerary embryos for procurement of human embryonic stem cells.

India has allowed establishment of new HESC lines with spare, supernumerary embryo with prior approval of the Institutional Committee for Stem Cell research and Therapy (IC-SCRT) and Institutional Ethics Committee (IEC)

provided appropriate consent is obtained from the donor as per the draft guidelines.

#### **Need of Definitive Legislation:**

Since the spare embryos created during infertility treatment are the most valuable source of embryos, India lacks in having a definite legislation regulating artificial reproductive technologies (ART). The existing guidelines directing stem cell research including embryonic stem cell are prepared by the Indian Council for Medical Research (ICMR).

These recommending guidelines have two inherent defects. One, these guidelines do not have any legal effect and second, it has no penal provisions for violating the rules/policies mentioned in these guidelines.

The absence of effective legislation will raise serious objection regarding the rights of the donor of embryos, number of spare embryos, quality of the embryos, preservation and disposal of frozen embryos etc.

The presence of definite enactment will help to regulate the activities of ART clinics by imposing strict accountability and responsibility through penal provisions. Registration of ART clinics should be made mandatory and subjected to periodic supervision to ensure high standard of norms, care, quality of treatment and facilities offered by them specifically in view of use, disposal and preservation of embryos.

The rights and autonomy of the donor couple and donor of gametes should be adequately protected. Informed consent of the donor regarding the use and destruction of the spare embryo should be taken. The question of financial compensation given to them should be adequately addressed keeping into mind the relevant existing rules and regulations of the country. Legislation similarly on the lines of the Human Fertilization and Embryo Act, as prevalent in the United Kingdom, will help to lessen the problems associated with ART.

#### Conclusions:

The possibilities offered by adult and embryonic stem cells in the treatment of various diseases have created widespread excitement globally. The clinical application of stem cells and its outcome is not yet clear and hence their potential use need to be ascertained by evidence before accepting them as safe and effective treatment.

Though stem cell based therapies are in early stage of clinical development later on they may turn out to be expensive in nature and thus affordable to only wealthy few. This might create social injustice and inequality and both are in violation of basic principles of clinical research.

The challenge is to ensure that it is available to all patients who need them.

The issues related to the source of embryonic tissues still lie unresolved and many more are likely to appear especially if non-embryonic sources of pluripotent stem cells become available. The science of medicine is always evolving and any new scientific discovery is associated with some or the other ethical or legal issue.

Ethical issues will remain, but they are the issues that arise in bringing any new discovery out of the lab into clinical research and then clinical use. The more apt and liberal use of ethical and legal principles will help to resolve them and bring these discoveries in reality for the benefit of needy patients.

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