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Editorial

Stem Cell and Ethical Issues

Stem cells are unspecialized cells characterized by ability to differentiate in to other cell types and self-regenerate. In 1998, James Thomson (University of Wisconsin – Madison) isolated cells from the inner mass of blastocyte, and developed the first human embryonic stem cell line in culture. Stem cells can be used to generate healthy and functioning specialized cells which can then replace diseased or dysfunctional cells. It is similar to the process of organ transplantation only, the treatment consists of transplanting cells instead of organs.

There are two types of stem cells. 1. Embryonic stem cells (ESC), 2. Adult stem cells (ASC) (Somatic stem cell). Embryonic stem cells are obtained from the inner cell mass of embryo at blastocyte stage. ES cells are pleuripotent, immortal, maintain normal karyotype. Adult stem cells are undifferentiated cells found among specialized or differentiated cells in a tissue or organ after birth, and they play a role during replacement of damaged and injured tissue. Hematopoietic stem cells from cord blood can be banked and are widely used for allogeneic and autologous stem cell transplantation in pediatric hematological diseases as an alternative to bone marrow transplantation. The existence of hematopoietic stem cells was discovered in the 1960, followed by the discovery of stromal cells (mesenchymal cells).

Only in the 1990's scientists confirm the reports of neural stem cells in mammalian brain, since then stem cells have been found in the epidermis, liver, and several other tissues. Adult stem cells can be isolated through plasmapherisis. Hematopoietic stem cells can differentiated into all three blood cell types as well as into neural stem cells, cardiomyocytes and liver cells.

Adult stem cells and cord blood stem cells do not raise special ethical concerns and are widely used in research and clinical care. Adult stem cells offer hope for cell therapy to treat diseases like, diabetes, Parkinson's disease, spinal cord injury, and myocardial infarction. If the patient's own cells (autologous stem cells) are used, immunological compatibility is not an issue.

Human embryonic stem cell (hESC) research is ethically and politically controversial because it involves the destruction of human embryo. The question of when human life begins has been highly controversial, because embryos have the potential to become human beings; if implanted into a woman's uterus at the appropriate hormonal phase, an embryo could implant, develop into a fetus, and become a live born child. Some people, however, believe that an embryo is a person with the same moral status as an adult or a live-born child. They believe that **"human life begins at conception"** and that an embryo is therefore a person, an embryo has interests and rights that must be respected. From this perspective, taking a blastocyte and removing the inner cell mass to derive an embryonic stem cell line is tantamount to murder.

Few people, however, believe that the embryo or blastocyte is just a clump of cells that can be used for research without restrictions, provided there is good scientific justification, careful oversight, and informed consent from the woman or couple for donating the embryo for research. A number of pro-life leaders support stem cell research using frozen embryos that remain after a woman or couple has completed infertility treatment and that they have decided not to give to another couple. U.S.Senator Orrin Hatch, on his senate website, states: "The support of embryonic stem cell research is consistent with prolife, pro-family values.

"I believe that human life begins in the womb, not a petridish or refrigerator… To me, the morality of the situation dictates that these embryos, which are routinely discarded, be used to improve and save lives.

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The tragedy would be in not using these embryos to save lives, when the alternatives is that they would be discarded".

Several ethical concerns come into play when a frozen embryo is donated.

1. Informed consent from the women or couple donating the embryo.
2. Consent from gamete donors involved in the creation of embryo.
3. Confidentiality of donor information.

Informed consent for donation of materials for stem cell research, has been regarded as a basic requirement in research with human embryo, for instance, a person might consider infertility research acceptable but object to research to derive stem cell lines lead to patents or commercial products. Hence, obtaining informed consent for potential future uses of the donated embryo is must.

Frozen embryos may be created with sperm or oocytes from donors who do not participate any further in assisted reproduction. Consent from gamete donors is not required for embryo research because they have ceded their right to direct further usage of their gametes to artificial reproductive technology (ART) patients. However, some may object to the use of their genetic materials for research. In one study, 25% of women who donated oocytes for infertility treatment did not want the embryos created to be used for research. Little is known about the wishes of sperm donor's concerning research. ART clinics can readily discuss donation for research with oocyte donors during visits for oocyte stimulation and retrieval. Most ART clinics obtain donor sperm from sperm banks and generally have no direct contact with the donors. Sperm is often donated anonymously to sperm banks, with strict confidentiality provisions.

Specific consent for stem cell research from both embryo and gamete donors was recommended by the National Academy of Sciences 2005 guidelines for human embryonic stem cell research. Confidentiality of donor information must be carefully protected in embryo and hESC research, because breaches of confidentiality might subject donors to unwanted publicity.

Files containing the identities of persons whose gametes or embryos were used to derive hESC lines should be protected through heightened security measures.

1. Any computer storing such files should be locked in a server room and password – protected, with access limited to a minimum number of individuals on a strict "need to know" basis.
2. Entry to the computer storage room should also be restricted by means of a card – key or equivalent system, that records each entry.
3. The files with identifiers should be copy – protected and double encrypted.
4. The computer storing these data should not be connected to the internet.

Human factors in breaches of confidentiality should also be considered, personal who have access to these identifiers might receive additional background checks, interviews, and training. Somatic cells can be reprogrammed to form pluripotent stem cells, these cells are called as induced pluripotentential stem cells (iPS cells). These iPS cell lines will have DNA matching that of the somatic cell donors and will be useful as disease models and potentially for allogeneic transplantation. iPS cells avoid the ethics of embryonic stem cell research because embryos or oocytes are not used. Furthermore, because a skin biopsy to obtain somatic cells is relatively noninvasive, hence iPS cells are "Ethically unproblematic and acceptable for use in human's. Neither the donation of materials to derive iPS cells nor their derivation raises special ethical issues.

Transplantation of cell derived from pluripotent stem cells offers the promise of effective new treatments. Some stem cell therapies have been shown to be effective and safe. ie., haematopoietic stem cell transplants for leukemia, and epithelial stem cell – based treatments for burns and corneal disorders. These clinical trials should follow eithical principles that guide all clinical research, including appropriate balance of risks and benefits, informed, voluntary consent, and also additional ethical requirements to strengthen trial design, coordinate scientific and ethics review, and ensure publication of negative findings. These measures are appropriate because of the highly innovative nature of the intervention, limited experience in humans and the high hopes of patients who have no effective treatments.

An institutional stem cell research oversight committee (SCRO) with appropriate scientific and ethical expertise as well as public members should be convened at each institution to review, approve and oversee stem cell research. hSC research offers exciting opportunities for scientific advances and new therapies, but also raises some complex ethical and policy issues. These issues need to be discussed along with scientific challenges to ensure that stem cell research is carried out in an ethically appropriate manner.

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