Committee: World Health Organisation

Issue: Discussing the ethical aspect of the donation of embryos to be utilized for embryonic stem cell research

Student Officer: Maria Siniolaki

Position: Deputy President

PERSONAL INTRODUCTION

Dear delegates,

My name is Maria Siniolaki and it is my honor to be serving as the Deputy President of the World Health Organisation in the 3rd ACGMUN Conference. I attend the 10th grade at Arsakeia Schools of Psychiko and this will be my 10th MUN conference. It's a great privilege for me to have the opportunity to serve as a Student Officer in this year's conference, which will be my first time serving in such position.

As a Deputy President, it is my duty to guide you through this topic and answer any questions you might have. I sincerely hope that you will find this Study-Guide helpful and a valuable first introduction to the topic. In case you have any further questions feel free to contact me via email at msiniolaki@gmail.com.

I am looking forward to meeting all of you at the conference!

Best Regards, Maria Siniolaki

TOPIC INTRODUCTION

DNA cloning has proved very beneficial for medical and healthcare issues, especially when it comes to therapeutic cloning. The promise of new therapeutic avenues for the treatment of a range of conditions has led researchers to consider the use of stem cells. These cells have the capacity to become some or even all of the 206 different cell types found in the human body. Stem cells come in a wide variety of types. Adult stem cells have been found in nearly every tissue of the human body, where they carry out a role in tissue regeneration. Embryonic stem cells are located in the human embryo at the blastocyst stage. Embryos at this age are often

unwanted in reproductive technology treatment, and some parents have donated them for research. The key ethical issues concern the destruction of human embryos for stem cell derivation. On the grounds that the human embryo is a human life with moral value justifying its protection, the extraction of embryonic stem cells is unethical. The use of adult stem cells have generally been considered to be free of any particular ethical issues. One limitation to the possible use of embryonic stem cells in therapy is that they will likely be rejected by the recipient. In an attempt to overcome this researchers are attempting to produce cloned human embryos to derive genetically near-identical stem cells for possible treatment. However, all these therapeutic lines derived from embryonic stem cell research are highly controversial on the ethical aspects.

DEFINITION OF KEY TERMS

Embryonic stem cell

Cells obtained from an embryo in the blastula phase, when they are still only a few days old. Because they have only begun to differentiate, these cells have the capability of developing into any cell in the human body, a fact which makes them potentially important in medicine. ¹

Therapeutic cloning

The permitted creation of cloned human tissues for surgical transplant.²

Bioethics

A field of study concerned with the ethics and philosophical implications of certain biological and medical procedures, technologies, and treatments, as organ transplants, genetic engineering, and care of the terminally ill.³

Pro-life movement

A social movement about advocating the legal protection of human embryos and fetuses, especially by favoring the outlawing of abortion on the ground that it is the taking of a human life. 4

¹ www.dictionary.com

² www.dictionary.com

³ www.dictionary.com

⁴ www.thefreedictionary.com

In Vitro Fertilization

In vitro fertilization (IVF) is a procedure in which eggs (ova) from a woman's ovary are removed. They are fertilized with sperm in a laboratory procedure, and then the fertilized egg (embryo) is returned to the woman's uterus. 5

Differentiation

The normal process by which a less specialized cell develops or matures to become more distinct in form and function. 6

Oocyte

An immature egg cell of the ovary; in humans, one oocyte matures during the menstrual cycle, becoming an ootid and then an ovum, while several others partially mature and then disintegrate.⁷

The Hinxton Group

The Hinxton Group is an informal collection of individuals interested in ethical and wellregulated science, which explores the ethical and policy challenges of transnational scientific collaboration in regulations governing embryo research and stem cell science.⁸

National Institutes of Health

The National Institutes of Health (NIH) is an important U.S. health agency, devoted to medical research. Administratively under the Department of Health and Human Services (HHS), the NIH consists of 20 separate Institutes and Centers. ⁹

BACKGROUND INFORMATION

Therapeutic cloning and Embryonic stem cells

The advancement in biotechnologies and stem cell research offers a tremendous potential in regenerative medicine and in the treatment of genetic defects, even though it encounters many scientific difficulties, legal constraints and ethical roadblocks. Therapeutic cloning is the transfer

⁵ www.medical-dictionary.thefreedictionary.com

⁶ www.biology-online.org

⁷ www.dictionary.com

⁸ www.hinxtongroup.org

⁹ www.medicinenet.com

of nuclear material into an enucleated oocyte with purpose to derive embryonic cell lines with the same genome as the nuclear donor. Distinguishing the two terms, the aim of reproductive cloning is the creation of a person, while the goal of therapeutic cloning is to generate and direct the differentiation of patient-specific cell lines isolated from an embryo. However, laws regarding biomedicine do not distinguish reproductive from therapeutic cloning.

Embryonic stem cells are pluripotent stem cells derived from an early stage pre-implantation embryo, 4–5 days after fertilization. Isolating the embryoblast results in the destruction of the embryo and consequently, in the destruction of any potential life, a process which raises ethical issues. Researchers are focusing on the therapeutic potential of embryonic stem cells, with many clinical use. Potential uses include the treatment of spinal cord injuries, age related macular degeneration, diabetes, neurodegenerative disorders (such as Parkinson's disease), AIDS etc. However, adverse effects in the research and clinical processes such as tumours and unwanted immune responses have also been reported.

Existing embryonic stem cell lines

In 2001, President Bush, who is pro-life supporter, allowed National Institutes of Health (NIH) funding for stem cell research using embryonic stem cell lines already existing at the moment, while prohibiting NIH funding for the derivation of additional embryonic stem cell lines. This policy is based to the widespread belief that hESC (human Embryonic Stem Cell) research held great promise for treating degenerative diseases, while still opposing further destruction of human embryos. Such policies were adopted at the time by many countries, allowing research to be carried out on the stem cell lines, which may allow benefits to come out of the embryos destruction. However, using only existing embryonic stem cell lines is scientifically problematic. Originally, over 60 hESC lines were widely acceptable for funding but as it turned out, most of these lines were not suitable for research. Although, since 2009, 22 hESC lines are eligible for funding, these lines may not be safe for transplantation into humans, and some of them have been shown to accumulate mutations, including several kinds of cancer. It is widely believed that a lack of access to new embryonic stem cell lines hinders progress toward stem cell research. Currently, funds aren't used to derive new embryonic stem cell lines. Funded equipment and laboratory space isn't used for research on non-approved hESC lines. The derivation of new hESC lines and research with hESC lines not approved by Health Authorities may be carried out by private sector. However, a number of states have established programs to fund stem cell research, including the derivation of new embryonic stem cell lines. It is now expected that funding will be made available to derive new hESC lines from frozen embryos

donated for research after a woman or couple using in vitro fertilization (IVF) has stated they are no longer needed for reproductive purposes.

New embryonic stem cell lines from frozen embryos

Women and couples nowadays undergo infertility treatment and have frozen embryos remaining after they complete their treatment. A very difficult decision for them to make is the disposition of these embryos. It is really common for them to choose to donate the remaining embryos to research rather than giving them to another couple for reproductive purposes or destroying them. However, several ethical concerns are raised when a frozen embryo is donated, including informed consent from the woman or couple donating the embryo, consent from gamete donors involved in the creation of the embryo, and the confidentiality of donor information. Consent is particularly important in research with human embryos. Some donors consider all embryo research to be unacceptable, while others only support some forms of this kind of research. The obtaining informed consent for future uses of the donated embryo respects this diversity of views. Moreover, regulations on research permit a waiver of informed consent for the research use of deidentified biological materials that cannot be linked to donors. Materials such as oocytes that fail to fertilize or embryos that fail to develop sufficiently to be implanted during IVF procedures, could be deidentified and then used by researchers. In addition, when infertility patients have frozen embryos remaining, they are contacted by the IVF program to decide whether they want to continue to store the embryos or to discard them. If the patients choose to discard the embryos, it would be possible to use them for research.

The concept of oocyte donation

The medical risks of oocyte retrieval include ovarian hyperstimulation syndrome, bleeding, infection, and complications of anesthesia. Because of these risks, women donating oocytes for research should be protected against the costs of medical expenses and oocyte retrieval. As a matter of fairness, women who undergo an invasive procedure for the benefit of science and who are not receiving payment beyond expenses should not bear any costs for the treatment of complications, especially in countries that does not have a universal health insurance. If women in infertility treatment share oocytes with researchers their prospect of reproductive success may be compromised because fewer oocytes are available for reproductive purposes. In this situation, the expert carrying out oocyte retrieval and infertility care should give priority to the reproductive needs of the patient in IVF. Unfortunately this is not always the case in oocyte retrieval procedures.

The ethical debate

Research with embryonic stem cells (ESCs) is highly debated and many people have strong opinions about it. Both sides of the debate are interested in protecting human life and it comes down to how the human blastula is viewed. As mentioned before, ESCs are primarily made from cells found in a human blastula, one of the earliest stages of human life. Blastulas used in research are typically harvested, isolated and cultivated in a laboratory or fertility clinic. Stem cell research thus raised difficult questions such as, does life begin at fertilization, in the womb, or at birth? Is a human embryo equivalent to a human child? Does a human embryo have any rights? Might the destruction of a single embryo be justified if it provides a cure for a countless number of patients? Since ESC can grow indefinitely in a dish and can, in theory, still grow into a human being, is the embryo really destroyed? All these questions raised are the base for debate upon the ethical aspect of embryonic stem cell research. Both sides of this debate are protecting life in different ways that's why this topic is consider as one of most controversial scientific dilemmas. From one point of view, supporting such research is completely ethical as it's aiming towards the progress of medicine and the creation of new treatments for many incurable diseases, thus a breakthrough for the humankind. From the other part, for those who support that an embryo is equivalent to a human child, these researches are considered "murder". According to the supporters of the pro-life movement the embryo is consider a human being that's growing through all 9 months of pregnancy. More precisely, they justify their position with the idea that since it has human DNA, that makes it a human with rights and in our case with the right to life. Additionally, its DNA is different from either its mother or father, so it clearly not just a tissue growth of the father or the mother. Thus, it is not acceptable for them to intercept to the growth of this human being and destroy the embryo since by isolating the blastula, every potential for future life is gone. Thus, the root of the ethical debate are the different beliefs on when human life begins. However, these views are not only existing among scientist and researchers but also among states as shown through the policies they choose adopt.

MAJOR COUNTRIES AND ORGANISATIONS INVOLVES

The Hinxton Group

In early 2004, members of the Stem Cell Policy and Ethics Program (SCOPE) at the the Johns Hopkins Berman Institute of Bioethics began developing a new project, aspiring to deal with the ACGMUN Study Guide Page 6 of 11

ethical matters of medical researches, such as ESC research. The 'Hinxton Group', decided that there were additional challenges they would be able and willing to address. The specific objectives of the project were to identify the primary challenges faced by scientists, universities, and journal editors with respect to international collaboration in stem cell research, explore the question of oocyte donation and related issues, and identify forwardlooking strategies to foster the scientific and ethical integrity of such research in a global context.

The National Institution of Health (NIH)

The NIH has funded most of ESC researches in the US and is the responsible authority for such researches. The National Institutes of Health Guidelines for Human Stem Cell Research were published on July 7, 2009. These Guidelines establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

The International Society for Stem Cell Research (ISSCR)

The International Society for Stem Cell Research is nonprofit organization established to promote the exchange of information and ideas relating to stem cells, to encourage the research involving stem cells, and to promote professional and public education in all areas of stem cell research and application. The ISSCR published the Guidelines for Stem Cell Research and Clinical Translation and also supports all forms of stem cell research, performed and advocates that embryonic, adult, and reprogrammed stem cell research must move forward in order to understand better diseases and identify treatments.

Countries involved

Most of the UN countries have already adopted specific policies upon the matter, which differentiate in each one of them. Most of these countries have signed relevant treaties and conventions. In addition, in many states there are Health Authorities which are exclusively responsible for monitoring, funding and governing such researches.

Singapore

Singapore is widely considered "Asia's stem cell center". It has more than 40 stem cell research groups in the country and authorizes the use, for therapeutic purposes, of embryos that are no more than two weeks old.

United Kingdom

The Human Fertilization and Embryology Act (HFEA) of 1990 and the Human Reproductive Cloning Act of 2001 permit the destruction of embryos for human embryonic stem cells. This is only permissible if the proposed research increases knowledge about the development of embryos or serious disease or enables such knowledge to be applied in developing treatments for serious disease. As a result, the United Kingdom is one of the leading centers for hESC research.

United States

Under the auspices of the Obama administration, the National Institutes of Health plans to expand federal funding for stem cell lines that meet certain ethical requirements: the embryo was discarded after IVF, informed consent was obtained from the donors, the couple does not receive compensation or are coerced or threatened. Older stem cell lines created in the spirit of the new regulations will be considered for federal funding, whereas embryos created solely for research purposes will be excluded.

BLOCS EXPECTED

Countries that prohibit or severely restrict the use of embryonic stem cell:

Netherlands
New Zealand
African Countries
South American Countries
Philippines
Saudi Arabia

Countries that have created the legal basis to support embryonic stem cell research:

Greece	Japan
Sweden	India
Spain	Iran
United Kingdom	Israel
Belgium	South Korea
France	China

Australia South Africa

Brazil

TIMELINE OF EVENTS

Date	Description of events
1978, July 25	First IVF birth
1999, December 1	Convention on Human Rights and Biomedicine
2000, August 25	NIH guidelines for research using human embryonic stem cells go into effect (USA)
2005, March 8	United Nations Declaration On Human Cloning
2013, May 15	Scientists Generate Human Nuclear-Transfer Embryonic Stem Cells/ Therapeutic cloning
2016, May 12	The Guidelines for Stem Cell Research and Clinical Translation are updated

RELEVANT RESOLUTIONS, TREATIES AND EVENTS

A/RES/59/280 Declaration on Human Cloning, approved by the United Nations General Assembly on March 8, 2005:

The statement was largely supported by Roman Catholic countries and opposed by countries with active embryonic stem cell research programs. Many Islamic nations abstained. The UN Declaration on Human Cloning, calls for all member states to adopt a ban on human cloning, which it says is "incompatible with human dignity and the protection of human life."

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine: It was opened for signature on 4 April 1997 and the issues addressed by this convention are the security of the dignity of human beings within the field of biomedicine as well the concepts of consent, private life and right to information, human genome, scientific research and organs and transplantation

National Institutes of Health Guidelines for Human Stem Cell Research, published on 7 July 2009: As mentioned before, these Guidelines establish policy and procedures under which the

NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

Guidelines for Stem Cell Research and Clinical Translation, updated on 12 May 2016 by ISSCR: The guidelines preserve the imperative for a specialized oversight process for research involving human embryos, in recognition of the unique sensitivities surrounding such research.

POSSIBLE SOLUTIONS

Countries that prohibit any kind of embryonic research a reconsideration of their strict regulation would be a feasible solution for states that have refused to fund such research, bearing in mind the profits of it in medicine and identification of treatments. In addition, they could introduce some of the applications of ESC research which have been considered as ethical by most parties, since they do not involve any kind of cloning and do not destroy potential future life as it's about deidentified biological materials etc.

Considering all countries, allowing therapeutic cloning instead of reproductive cloning and creating the legal basis for this kind of scientific research could be a solution. That is been proposed to avoid any accusation of violation of human rights and to avoid any further ethical debate upon the matter.

What is of great importance is for all states to define the stage at which the embryo is considered to be a human with moral rights so as to avoid any controversy on research ethical aspects. This would halt many conflicts among scientists but also would reduce the negative attitude of the public towards ESC research.

Another measure to be taken in order to balance the ethical dispute is the establishment of stricter legislation on the concept of consent when it comes to donations of embryos and/or oocytes for research.

As far as it concerns the concept of oocyte donation it is necessary for states to cover all medical expenses for the women who undergo such procedures. Requiring free care for short-term complications of oocyte donation is feasible even in countries without universal health insurance. But even if the women have insurance, additional expenses might come up. Commercial insurance policies are available to cover short-term complications of oocyte retrieval.

BIBLIOGRAPHY

1. www.bioethics.org.au/Resources/Resource%20Topics/Stem%20Cells.html

- 2. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726839/</u>
- 3. <u>https://www.khanacademy.org/science/biology/biotech-dna-technology/dna-cloning-</u> <u>tutorial/a/overview-dna-cloning</u>
- 4. <u>http://www.wisegeek.net/what-is-embryonic-stem-cell-research.htm</u>
- 5. <u>https://embryology.med.unsw.edu.au/embryology/index.php/Timeline</u> -<u>Human Embryonic Stem Cell Research</u>
- http://5859d7f0f30e9c1373ac-76f52f45edd080d6d6d41139c312cfe3.r43.cf2.rackcdn.com/uploaded/u/0e2950803 13 93615745 unonhumancloning.pdf
- 7. https://rm.coe.int/168007cf98
- 8. <u>http://www.isscr.org/about-isscr</u>
- 9. https://learn.genetics.utah.edu/content/stemcells/scissues/
- 10. https://whatisdna.net/dna-cloning/
- 11. http://www.hinxtongroup.org/au.html
- 12. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2323472/
- 13. <u>https://stemcells.nih.gov/research.htm</u>
- 14. https://www.britannica.com/topic/Declaration-on-Human-Cloning
- 15. <u>http://www.isscr.org/docs/default-source/all-isscr-guidelines/guidelines-2016/isscr-guidelines-for-stem-cell-research-and-clinical-</u>translationd67119731dff6ddbb37cff0000940c19.pdf?sfvrsn=4
- 16. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2744936/</u>
- 17. <u>https://www.ukessays.com/dissertation/examples/philosophy/ethical-issues-</u> <u>concerning-cloning.php</u>