

Dilemmas Concerning Embryonic Stem Cells Research.

Yasmany Gutierrez

West Coast University

Course Number: HA 500 Legal and Ethical Issues in Health Care Management 202105SUIOL

OL-A.

DR. Karen Powell

03-July-2021

INTRODUCTION

Human embryonic stem cells have become a subject of uninterrupted disagreement for religions, governments, and healthcare professionals worldwide due to the delicate areas covered by this type of research. The Catholic Church has expressed its opposition to the destruction of human embryos on several occasions throughout the years. In contrast, the views of protestant believers may differ depending on where they live. Despite the Catholic Church's reality that it rejects these investigations, embryonic stem cells in research are permitted in some countries where the Catholic Church is predominant. The United States government has encountered a diverse range of opinions regarding embryonic stem cells in human research. President George W. Bush was the most vocal opponent, and President Barack Obama was the most active supporter of such investigations. Embryonic stem cell research has also been supported by healthcare professionals who believe it is the solution for chronic diseases. Still, others have also questioned it due to ethical breaches, such as violating beneficence and autonomy related to these investigations.

ETHICAL/MORAL CONSIDERATIONS

Scientists from different countries have attempted to develop therapies to treat various diseases and other health problems throughout the years. However, a critical component must first be investigated to create such treatments: the initial phases of human development. Initial stages can occur because of fertilization, described as the fusion of a spermatozoid with an oocyte, creating a zygote. The zygote is the ultimate totipotent cell at this early stage of human development. It may grow into an embryo with all embryonic and extra-embryonic lineages on its own. Although it is considered the hallmark of this process, this totipotent cell has become controversial between religions, governments, and healthcare professionals (Li et al., 2017).

The use of embryos in research has been a source of contention among several religions. The Catholic Church is one of these religions that has consistently stated its disapproval. The central aim of this religion is to safeguard all innocent human lives, and it was established by Pope Paul VI on July 25, 1968, in Rome, Italy, with his papal letter "Humanae Vitae," which translates "Of Human Life." The Roman Catholic Church's position on family planning and reproductive problems like abortion, sterilization, and contraception were defended and reaffirmed in this letter. Furthermore, in the twenty-first century, the Pontifical Academy for Life issued a statement titled "Declaration on the Production and Scientific and Therapeutic Use of Human Embryonic Stem Cells," which outlined the significant grounds for the Catholic Church's long-standing objection to this sort of research. These crucial reasons were as follows: (1) an unethical act begins with the destruction of a human embryo, which is essential to produce embryonic stem cells, (2) embryos derived from the cloning process, while not generated traditionally, are recognized by the Catholic Church as actual humans, and should never be used

in research and, (3) existing embryonic stem cells should not be used in research since they were produced via the destruction of embryos. Thus, Catholics strongly believe that the destruction of human embryos in research is cruel and conflicts with their principles and beliefs (Richert, Scott P., 2021).

Although the Catholic Church has expressed opposition to the use of embryos in an experiment, countries such as Spain, where nearly 94 percent of the population follows this religion, authorizes embryos in research using remains from artificial fertilization. It is not reasonable to generalize that if a country's population is predominantly Roman Catholic, its laws will be hostile to human embryonic stem cell research. A similar scenario exists in protestant countries; most protestant countries have expressed approval for using these types of cells in human research; however, we cannot generalize that all protestants allow these investigations because conservative protestants and mainline protestants have differing perspectives on such research. For example, the United Kingdom is a predominantly Protestant country well-known for its liberal human embryonic stem cell research policies. On the other hand, Germany is a primarily Protestant country that restricts human embryonic stem cell research. In the United States, different from Germany, embryonic stem cell research is not currently forbidden. However, scientists can only utilize cell lines derived from leftover IVF embryos created before August 9, 2001, if the research is conducted with government funds (GaBI Journal, 2018).

Additionally, it has been observed throughout the years that there are differences of opinion about normative ethics and the use of embryonic stem cells. Applying the golden rule "We should do to others what we would like others to do to us" can demonstrate how normative ethics should be considered by countries where the use of human embryonic stem cells is

permitted. Other normative ethics theories, like utilitarianism, embrace the use of embryonic stem cells in research since the destruction of human embryos is seen as a procedure that may help to find therapies to treat patients with incurable diseases (Nursing Answers, 2020).

LEGAL CONSIDERATIONS

In the United States, legal restrictions on the use of embryonic stem cells had existed since 1974, when Congress approved the National Research Act, which established standards for research involving human embryos and the necessity for an Ethics Group to review and authorize these research studies. In 1979, the Ethics Advisory Board (EAB) approved a protocol for using embryos in research, declaring these studies morally acceptable. A year later, the EAB was suspended, leaving no regulatory agency to review and authorize research methods involving human embryos. Because of the closure of this board, investigations using stem cells for therapeutic purposes were prohibited for an extended period. In 1988, the NIH established the Human Fetal Tissue Transplantation Research Panel, and this group favored the utilization of funding for embryonic research. In 1990, the Department of Health and Human Services (HHS) declined to approve the panel's proposal, thereby restricting the use of embryonic stem cells. Congress subsequently tried to reverse this decision, but President George H.W Bush rejected the proposal. This prohibition was eventually released in 1993, as requested by President Bill Clinton when Congress passed the NIH Revitalization Act, which authorized federal funding for fetal tissue transplantation research. In 1996, Congress passed the Balanced Budget Downpayment Act, which includes the Dickey-Wicker Amendment, which forbids federal funds to produce human embryos for scientific purposes or research involving the destruction of human embryos. A few years later, in 2000, the NIH issued new guidelines on embryonic stem

cell research, specifying that cells utilized in these studies must meet the following criteria: (1) obtained through the purchase of frozen embryos from reproductive clinics using private funding, (2) embryos created solely for the intention of fertility treatment, (3) embryos that were created for infertility treatment but are no longer needed by the donors and (4) consent of the donor must be obtained. A new policy banning government funding for research involving embryonic stem cells derived from cell lines that had been generated on or after August 9, 2001, was announced by President George W. Bush following the release of these new guidelines by the NIH. This policy does not appear to have impacted private sector or state research or adult stem cell research. In 2005, the House of Representatives made another attempt to use federal funds in these investigations, describing that those embryos created but not used in the IVF process could be used in research. The Senate also approved this bill, agreeing with the House decision, but President Bush refused to accept it. President Bush's opposition to the use of government funding for these studies was reiterated in 2007 when the Senate approved its version of the Stem Cell Research Enhancement Act, which had bipartisan support from both the Republican and Democratic parties (Research America, 2019).

Even though previous administrations often rejected this controversial topic, in 2009, the use of embryonic stem cells with federal funds was authorized during Barack Obama's presidency. The Dickey-Wicker Amendment was replaced with the Omnibus Appropriations Act. In 2016, President Obama signed the Cures Act of the 21st Century, which included measures to ensure timely regulatory consideration of regenerative therapy involving stem-cell treatments. The Food and Drug Administration (FDA) of the United States published guidelines on regenerative medicine, including treatments generated through stem cell research, a year later to

limit regulatory breaches that clinics were using to offer unapproved stem cell therapies to patients. In 2019, the Department of Health and Human Services established a new regulation creating an Ethical Advisory Board to assess research proposals utilizing fetal tissue to determine whether they should be eligible for government funding. The Human Fetal Tissue Research Ethics Advisory Board had its inaugural meeting in 2020. A total of 14 research proposals involving the use of fetal tissue were reviewed, with only one project being recommended for federal funding out of the whole pool of submissions. Currently, the Department of Health and Human Services has updated its policy so that NIH-funded extramural research involving fetal tissue will no longer require approval by an Ethics Advisory Board, and intramural research involving fetal tissue can restart (Research America, 2019).

Sherley v. Sebelius (2010) is a court case that should be studied while addressing this subject. In this case, a scientist from the Boston Biomedical Research Institute filed a lawsuit to stop the Obama administration executive order from 2009 that extended embryonic stem cell research. Obama's executive order offered government support to embryonic stem cell research that those reproductive clinics would otherwise discard. James Sherley (scientist) claimed that this order would prohibit his team from receiving government funds to conduct research using adult stem cells. A federal judge ruled in Sherley's favor, stating that the executive order violated a law that prohibits government funding of any study that destroys embryos. However, the U.S. Supreme court for the District of Columbia eventually decided to reverse the judge's decision, and the Supreme Court refused to consider the case (MD Linx, 2020).

INTERPROFESSIONALISM

Embryonic stem cell research has been controversial among religious leaders, countries, U.S. presidents, and healthcare professionals working in various fields. After a group of American scientists successfully extracted stem cells derived from human embryos in November 1998, this topic became extensively debated among healthcare professionals due to the benefits and drawbacks of using embryonic stem cells in clinical research. Human embryos can turn into stem cells applied in clinical research because of two essential characteristics. First, they are undifferentiated cells, which means they may divide and regenerate themselves even after extended periods of inactivity. As a second characteristic, embryonic stem cells are totipotent, meaning they can differentiate into specific tissue or cells depending on physiological conditions. As a result of these characteristics, healthcare supporters consider embryonic stem cell research might assist in developing new and more effective therapies for serious diseases, such as Parkinson's disease and Alzheimer's disease, alleviating the agony and suffering of many people (Voices of Bioethics, 2019).

On the other hand, those opposed to embryonic stem cell research consider that the possibility of scientific advantages does not justify the immoral act of interfering with the natural process of fetal development and meddling with the human embryo's right to life. Human embryo destruction for research is unethical because it breaches the beneficence principle represented in the Belmont Report, which establishes the fundamental ethical principles and standards used in studies where humans participate. Stem cell researchers also show a disregard for the autonomy and well-being of human embryos destroyed in stem cell research. Furthermore, the concept of beneficence is breached while safeguarding the reproductive interests of women undergoing infertility treatment who rely on embryo donations to resolve

their infertility. Patients' chances of successful infertility treatment may be endangered since fewer embryos are accessible for reproductive purposes because of embryonic stem cell research. The number of embryos required to become fully grown and undergo embryonic stem cell research would probably outnumber the amount of accessible frozen embryos in fertility clinics, contributing to the shortage of sources for women experiencing infertility. As a result, these research's investigations threaten female reproductive autonomy, thereby breaching beneficence. Finally, other ethical issues arise in the study of embryonic stem cells due to viable alternatives that do not need the destruction of human embryos. It seems that embryonic stem cells are more dangerous to a patient's health than beneficial. Because of their ability to multiply and differentiate, embryonic stem cells have a higher risk of triggering tumor growth in the patient's body after transplanted. Embryonic stem cells are also at increased risk of immune rejection. Given that embryonic stem cells are derived from IVF embryos when implanted in the body, their proteins will be misidentified by the patient's immune system, resulting in the destruction of these cells as a defensive response to protect the patient's body (Voices of Bioethics, 2019).

Interpretations of the Hippocratic Oath have also created controversies surrounding the use of embryonic stem cells in research. According to Jonathan Sussman's article " Stem Cells: A Case for the Use of Human Embryos in Scientific Research," the contemporary version of this oath emphasizes that investigators must use any necessary resources for the treatment of the sick. However, medical professionals may use the oath principle "do no harm" to express their opposition to the use of embryonic stem cells in clinical research (VCE, 2020).

CONCLUSION

Embryonic Stem Cell research is a highly controversial topic that has sparked debate among researchers for several generations. Fortunately, with the discovery of induced pluripotent stem cells (iPS), which can be transformed into any type of cells needed for an investigation, embryonic stem cells may be disregarded and no longer required in clinical research.

References

- GaBI Journal. (2018). *The impact of religion on human embryonic stem cell regulations: comparison between the UK, Germany, and the U.S.*
<http://gabi-journal.net/the-impact-of-religion-on-human-embryonic-stem-cell-regulations-comparison-between-the-uk-germany-and-the-us.html>
- Li, S., & Winuthayanon, W. (2017). Oviduct: roles in fertilization and early embryo development. *The Journal of endocrinology*, 232(1), R1–R26.
<https://doi.org/10.1530/JOE-16-0302>
- MD Linx. (2020, September 3). *Legal Matters*. Court rulings that changed medicine
<https://www.mdlinx.com/article/court-rulings-that-changed-medicine/147FEf8WGxGdBQI4b8HG7u>
- Nursing Answers. (2020, February 11) *Essays*. Stem Cell Research and Utilitarianism.
<https://nursinganswers.net/essays/stem-cell-research-utilitarianism-4154.php>
- Research America. (2019). *Advocacy-action*. A brief history of U.S. stem cell policy.
<https://www.researchamerica.org/advocacy-action/issues-researchamerica-advocates/stem-cell-research/brief-history-us-stem-cell>
- Richert, Scott P. (2021, February 16). *The Catholic Church's Stance on Various Forms of Stem-Cell Research*. Retrieved from
<https://www.learnreligions.com/teaching-on-stem-cell-research-542808>
- VCE. (2020, May 19). *Volume 4 ISSUE 1*. Stem Cells: A Case for the Use of Human Embryos in Scientific Research.

<https://vce.usc.edu/volume-4-issue-1/stem-cells-a-case-for-the-use-of-human-embryos-in-scientific-research/>

Voices of Bioethics. (2019, March 6). *Embryonic Stem Cell Research*. An Ethical Dilemma.

<https://journals.library.columbia.edu/index.php/bioethics/article/view/6135>