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COMMITTEE: World Health Organisation
TOPIC: The Question of defining a Regulation for the use of Stem Cells
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INTRODUCTION

There is at present a considerable body of researchers who wish to engage in research on a type of human cell known as stem cell. This research, they argue, will bring great benefits in that it might lead to the development of transplantable tissues as therapies for a wide range of human illnesses, which are currently considered difficult or impossible to treat. However, the stem cells which they are particularly interested in are derived from the human embryo. This gives rise to the question as to whether it is ethically acceptable to take cells from a human embryo, prior to its implantation in uterus, in order to cultivate and analyse these cells in the laboratory for therapeutic research.

KEY WORDS

Stem Cells: stem cells are undifferentiated cells able to give rise to a number of other specialized cell types. Their two important properties, self-renewal (ability to divide many times while maintaining an unspecialized state) and potency (the ability to differentiate into specialized cells), make them valuable as a source of cell lines for research and therapy. Two types of stem cells are important in medicine research; embryonic stem cells and adult stem cells which occur in some tissues of adults and children. The potential applications include tissue engineering and cell terapy to replace diseased or damaged cells with new ones grown in culture.

Embryonic stem cells (ESCs) are pluripotent stem cells from the inner mass of blastocyst. Blastocysts are embryos of about 50-150 cells that are about five days old. When grown in vitro, ESCs retain their pluripotency (possibility to become any cells of the body) for many cell divisions, provided they are not stimulated to differentiate.

Adult stem cell (ASCs) are multipotent, because their ability to differentiate is limited to a relatively few cell type. Adult stem cells have been identified in many organs and tissues, including brain, bone marrow, blood vessels, skin….

Embryonic Stem Cell Cloning (ESCs cloning): the nucleus of the patient's cell is transferred into an egg that has had its nucleus removed, generating an embryo that is induced to grow. Isolated stem cells are cultured with the appropriate growth factors to grow into the required organ or tissue. Thus patient specific human embryonic stem cell could be used for therapeutic transplantation back into a patient or to study genetic diseases.

Induced Pluripotent Stem Cells (iPS cells), that is cells generated by reprogramming adult cells. The production of iPS cells is not very efficient (less than 1%); some of the reprogramming factors are oncogenes that bring with them a potential tumor risk.

Other sources of Stem Cells are the umbilical cord, the amniotic fluid and the placenta.

Treatments: Medical care given to a patient for an illness or injury.

Clinical trials: A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

Embryo: An organism in the early stages of growth and differentiation, from fertilization to the beginning of the third month of pregnancy (in humans). After that point in time, an embryo is called a foetus.

EXPLANATION OF THE TOPIC

Emerging biotechnologies pose public health challenges because of both the known and unforeseen risks they carry, the uncertain medical benefits they offer, the speed at which they have been disseminated and their unproven mode of application. The development of therapies from advances in stem cell science reveals the need to pay critical attention to stem cell treatments. Stem cells have attracted scientific, clinical and public interest because they are self-renewing and have the capacity to develop into specific cell types (known as biological plasticity), depending on the source of the stem cells. The hope is that stem cells could be used either to replace damaged cells or to create an environment for cellular regeneration to treat several conditions, including osteoarthritis, diabetes, macular degeneration and Parkinson disease.

Although promising in theory, so far very few stem cell therapies have proven to be safe and effective in clinical trials. Yet, despite the absence of evidence to support their use, there has been a global proliferation of clinics and associated businesses offering stem cell-based interventions to patients having serious medical conditions. These clinics operate mostly in the private health-care sector and typically market their interventions directly to patients over the internet. The emergence of these clinics has not only created domestic markets in many high-income countries, but has also fomented stem cell tourism – the movement of people across international boundaries to access alleged stem cell treatments. The global reach of this expanding industry exploits weaknesses and differences in national regulatory infrastructures and has revealed the need for an international approach to report and monitor the harms and benefits of these alleged treatments.

An adult stem cell is thought to be an undifferentiated cell, found among differentiated cells in a tissue or organ. The adult stem cell can renew itself and can differentiate to yield some or all of the major specialized cell types of the tissue or organ. The primary roles of adult stem cells in a living organism are to maintain and repair the tissue in which they are found. Scientists also use the term somatic stem cell instead of adult stem cell, where somatic refers to cells of the body (not the germ cells, sperm or eggs). Unlike embryonic stem cells, which are defined by their origin (cells from the preimplantation-stage embryo), the origin of adult stem cells in some mature tissues is still under investigation.

Research on adult stem cells has generated a great deal of excitement. Scientists have found adult stem cells in many more tissues than they once thought possible. This finding has led researchers and clinicians to ask whether adult stem cells could be used for transplants. In fact, adult hematopoietic, or

blood-forming, stem cells from bone marrow have been used in transplants for more than 40 years. Scientists now have evidence that stem cells exist in the brain and the heart, two locations where adult stem cells were not at first expected to reside. If the differentiation of adult stem cells can be controlled in the laboratory, these cells may become the basis of transplantation-based therapies.

The ethical legitimacy of performing human embryonic stem cell research depends, in large measure, on the status which is attributed to the embryo. Although there are other considerations having a bearing on the ethical question - such as the consent of the "owners" or creators of the embryo (the parents) - the categorizing of the embryo is crucial to the question of what can be done with it. Much of the ethical debate in this area has been taken up with the question of just what the embryo is. If the embryo is a human being (or person) then our treatment of it is limited to that which we are allowed to do to other human beings. If, by contrast, it is no more than a collection of human cells, then there are far fewer restraints on our handling of it. Mid-way views on the embryo allow for varying degrees of restraint on its use.

A solution to solve ethical problems and immune response in a recipient could be the use of Embryonic Stem Cell Cloning. A second solution is to use the technique to produce induced pluripotent stem cells (iPS cells). For both techniques and to reduce the risks of their use it's important to improve the scientific research.

As mentioned before, determination of the moment at which human life begins is pivotal in stem cell debates. Ensoulment is defined as the time when the entity becomes a human being, based on many religions' perspectives, although the moment when the soul arrives is long disputed. For example: **Judaism** considers the extracorporeal embryo in the pre-implantation stage as genetic material, so stem cell research is permissible according to most branches of Judaism. A human embryo is not considered as sacred until the fourth month of pregnancy, according to most Jewish scholars. Owing to this fact, research on stem cell and human embryos is allowed in this period. In **Christianity**, the current dominant belief is that ensoulment occurs at the moment of conception. Despite strong opposition of Catholics to stem cell research, **Protestants** have a wider range of views. Less conservative Protestant Christians support stem cell research at least before the development of the primitive streak at 14 days after fertilization. Most **Muslim** thinkers accept embryonic stem cell research, although there are obstacles to the research in some Islamic countries. According to Islamic teachings, decisions on stem cell research and cloning research should be based on advantages and limitations. Considering inevitable consequences of reproductive cloning, it is prohibited by many Muslim religious authorities; however, stem cell research and cloning for therapeutic purposes is sometimes permissible with precautions in pre-ensoulment stages of foetus development.

NATIONS AND ORGANIZATIONS INVOLVED

Failure to effectively regulate the stem cell industry may have a range of detrimental effects on patients, their families, public health systems, research and public trust in stem cell science and biomedical science in general. Given the local and global significance of these threats, it is important to consider the role of global organizations, particularly the World Health Organization (WHO), in regulating and containing the stem cell industry.

The ethical, social and public concerns raised by stem cell interventions have prompted the International Society of Stem Cell Research (ISSCR), an independent, non-profit organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells. It aims to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application. Another stem cell organization recognized internationally is the International Stem Cell Forum (ISCF) which is made up of 14 leading funders of stem cell research from a stem cell research, with the overall aim of promoting global good practice and accelerating progress in this vitally important area of biomedical science.

While such voluntary guidelines are useful, they lack the political, legal and moral authority that guidelines from WHO may offer. Furthermore, if WHO were to adopt stem cell product regulations under Article 21 of its Constitution, all Member States would be required to take the corresponding legislative steps unless they expressed reservations. This move would also help to strengthen national regulatory landscapes and assist sovereign governments to face potential political opposition to such regulation.

There is precedent for such action because WHO has previously addressed regulatory, governance and health issues associated with other health industries that run parallel to, or counter, established health systems and clinical practices. For example, following WHO *Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicines*, some Member States have chosen to regulate practices and products of traditional, alternative and complementary medicines.

If the adoption of regulations under Article 21 proved until now to be politically challenging, WHO could instead develop a code of practice drawn from the ISSCR guidelines. This would encourage sharing and gathering of evidence on safety and efficacy before the commercial provision of stem cells, and clarify the ethical principles that should underpin national laws and regulations regarding clinical practice.

Other possible roles for WHO might be to: provide much-needed technical guidance to resource-poor countries; use its mechanisms to gather and disseminate expert advice; convene expert advisory panels and committees on issues regarding the manufacture, licensing, regulation and proper use of stem cells; provide a platform for cross-jurisdiction information sharing; and establish a global governance framework for monitoring countries' progress in regulating the stem cell industry. Such a platform may encourage cross-country learning and help identifying and aligning best practices in the standards of care across jurisdictions.

To tackle the issues associated to the national and international under-regulation of the stem cell industry, a global strategy needs to be put in place. This strategy, which could be developed by WHO, should moderate the global stem cell industry, protect global health and public safety and promote future research to increase the evidence base of the stem cell industry.

At the national level, research on human embryos is permitted in some countries (with varying degrees of supervision), while it is expressly prohibited in others.

The second category includes **Ireland**, where Article 40 of the Constitution implicitly prohibits research on the embryo by stating the right to life of the "unborn child" equal to that of the mother. In **Germany**, the Law of 1990 on Embryo Protection regards as an offence the fertilization of an ovum for purposes other than its re-implantation in the donor; it takes the same position on the fertilization of a larger number of ova than can be implanted. In **Tunisia**, the National Medical Ethics Committee has stated its opposition to all experimentation on the embryo which is regarded as a "potential person" (Opinion No.1 of December 1996) and also to any form of cloning (Opinion No. 3 of May 1997).

In a number of other countries, the use for research purposes of embryos donated by persons following a treatment against sterility and not intended for implantation (supernumerary embryos) is permitted. In general, the conditions imposed are the prohibition of research after the 14th day of existence of the embryo and the consent of the couple who supplies the embryo. That is the case, for example, in **Canada**, **Sweden** (Law No. 115) and **Finland** (Law No. 488/1999).

In September 2000 the Observatory of Law and Bioethics of Barcelona, **Spain** did express its support for the creation of embryos for research purposes, both by donation and by cloning techniques.

In **Australia**, the law varies between different States and Territories, and in some of them the subject is not regulated by law. For such cases, the Australian National Health and Medical Council have formulated guidelines (The Ethical Guidelines on Assisted Reproductive Technology, paragraph 6) which, although not legally binding, are influential.

Finally, other countries are envisaging authorization of the creation of embryos for research purposes. In the **United Kingdom**, since 1990 the Human Fertilisation and Embryology Act authorises the use of supernumerary embryos for restricted research purposes - in particular concerning reproductive medicine and for the diagnosis of genetic and chromosomal disorders - and the production of embryos for these purposes. The House of Lords passed a law which permits the cloning of human embryos to derive stem cells, thus allowing the possibility of therapeutic cloning.

ACTIONS TAKEN

At the international level, there are few regulatory provisions concerning research on human embryos. Many texts proclaim the right to life in general, e.g. the Universal Declaration of Human Rights (Art. 3), the International Covenant on Civil and Political Rights (Art. 1) or the African Charter on Human and Peoples' Rights (Art. 4). Others more specifically proclaim the right to life of the conceived child, e.g. the American Convention on Human Rights, which stipulates that "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".

At the European level, the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997 does not resolve the matter of the permissibility of embryo research and leaves each country responsible for legislating on this matter. They must stipulate two conditions: the prohibition of producing human embryos for research purposes, and the adoption of rules designed to assure adequate protection for the embryo.

The Charter of Fundamental Rights of the European Union, adopted in Nice, France in 2000, expressly prohibits eugenic practices[1] and reproductive cloning, but does not comment explicitly on embryo research.

The European Group on Ethics in Science and New Technologies to the European Commission (EGE) adopted Opinion No. 15 on the ethical aspects of human stem cell research and use, in which it states

1 Eugenics is a medical discipline that aims to promote and develop the innate qualities of a breed, using the laws of genetic inheritance.

that “stem cell research based on alternative sources (spare embryos, foetal tissues and adult stem cells) requires a specific Community budget”, while pointing out that “it is up to each Member State to forbid or authorise embryo research”. On the other hand, the Group considers “ethically unacceptable” the creation of embryos with donated gametes for the purpose of deriving stem cells, and “premature” the creation of embryos by somatic nuclear transfer.

CHAIR’S SUGGESTIONS

The main question is whether stem cells should be considered human beings from the very beginning of conception, or if human beings begin after a certain period of time (for example, when they develop into a foetus). This question opens up the discussion as to whether human stem cells should be used (with varying levels of regulation) or prevented. This is because the use of human stem cells brings up a number of ethical issues and consequences including, the potential disregard for human rights, damaging, and potentially costly and/or ineffective medical treatments.

More specifically when we talk about ethical issues, two fundamental moral principles are brought to attention: one principle enjoins the prevention or alleviation of suffering, and the other enjoins us to respect the value of human life. There is a case to be made that the harvesting of human embryonic stem cells violates the second principle in that it results in the destruction of human life with value (i.e. human embryos). Accordingly, both principles apparently cannot simultaneously be respected in the case of embryonic stem cell research, to obtain embryonic stem cells, the early embryo has to be destroyed and this means destroying a potential human life. The question then is which principle should be given priority in this conflict situation; to permit embryonic stem cell research because of its potential benefits for overall human health? Or to prohibit embryonic research since it potentially violates respect for the value of the embryo as the very beginnings of a conceivable human life?

It is important to get a clear idea of what moral weight each side of the equation has. This will involve developing a sound and accurate picture of what the real value is of the benefits of embryonic research, and clarifying what the value of stem cells might consist in, and what, if anything, may be wrong with destroying them, always taking into consideration the position of your Country towards the question.

SOURCES

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