Forum

Stem cell research – the regulatory framework in South Africa

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The medical industry has, over the past couple of decades, seen remarkable development in the use of stem cells for therapeutic and research purposes. This is despite opposition from various radical groups, who argue, specifically in relation to the use of embryonic stem cells, that such use involves the creation, use and destruction of stem cells, which is unethical and tantamount to murder.

In South Africa, chapter 8 of the National Health Act, which deals with the use of stem cells, is not yet in operation. This means that we have to rely on the provisions of the Human Tissues Act which are for the most part outdated in so far as they do not take into account the developments relating to stem cell research.

This paper discusses the current regulatory framework of stem cell research with specific reference to the provisions of the Human Tissues Act, 1983 and the National Health Act, 2003.

The medical industry has, over the past couple of decades, seen remarkable development in the use of stem cells for therapeutic and research purposes. That is despite opposition from various radical groups,* who argue, specifically in relation to the use of embryonic stem cells, that the use of such stem cells involves the creation, use and destruction of human embryos which is unethical and tantamount to murder.[1] Despite the opposition against stem cell research and use, there is no doubt that cell-based therapy has the potential to positively change the medical industry as we know it. However, stem cell research and use must be conducted in a properly regulated framework and controlled environment to ensure patient safety. Unfortunately, this is currently lacking in South Africa.

Chapter 8 of the National Health Act,[2] which deals with the 'Control of use of blood, blood products, tissue and gametes in humans', is not yet in operation despite the National Health Act having been promulgated more than 8 years ago. This means that we have to rely on the provisions of the Human Tissues Act,[3] which are for the most part outdated in so far as the regulation of recent developments in stem cell research is concerned.

The provisions of chapter 8 of the National Health Act, once enacted, read with the regulations which have also been published but are not yet in operation, will allow for a properly regulated and controlled environment for the use of stem cells (including embryonic cells) for therapeutic and research purposes. There is therefore an urgent need for the implementation of the provisions.

This paper deals with the current regulatory framework for stem cell research with specific reference to the provisions of the Human Tissues Act and the National Health Act, the Constitution and the ethical issues relating to the use of embryonic stem cells. First, it examines the definition, sources and benefits of stem cell research.

Definition, sources and benefits

Stem cells are non-specialised cells which have the potential to create other types of cells such as blood, tissue, nerve or muscle cells.†[4] Some stem cell types may be able to create all other cells in the body, while others have the potential to repair or replace damaged tissue or cells – this has come to be known in the medical world as 'regenerative medicine'. There are three main sources for obtaining stem cells, namely embryonic stem cells, adult stem cells and umbilical cord cells.

Embryonic stem cells are cells extracted from an embryo after fertilisation but before implantation through a process called differentiation (a process whereby an unspecialised cell acquires the features of a specialised cell). Embryonic stem cells have the ability to generate all other cell types in the body, which distinguishes them from adult stem cells which can only produce a limited number of cell types.‡ Adult stem cells are cells that are extracted from the bone marrow and found in various adult tissues. They act as a repair mechanism to replace or renew damaged tissue. The richest source of stem cells is umbilical cord cells, which are cells that are extracted from the umbilical cord during pregnancy and stored in cell banks for future use.[5]

The benefits of stem cell-based therapy are immeasurable. Stem cells have been known to treat a variety of diseases including

*Embryonic stem cells are extracted from surplus embryos left over from *in vitro* fertilisation, killing the embryo in the process. Embryonic stem cell research (ESCR) is opposed by many pro-lifers, who feel that the embryos from which the stem cells are extracted are human persons. Since the embryos are killed when the stem cells are removed, most pro-lifers view the extraction procedure as murder and a form of experimentation on human bodies.

†Stem cells contribute to the body's ability to renew and repair its tissues. Unlike mature cells, which are permanently committed to their fate, stem cells can both renew themselves and create new cells of whatever tissue they belong to (and other tissues).

‡Stem cells found in umbilical cords have recently proven useful in treating the same types of health problems as those treated using bone marrow stem cells and PBSCs (peripheral blood stem cells). Umbilical cord blood stem cell transplants are less prone to rejection than either bone marrow or peripheral blood stem cells. This is probably because the cells have not yet developed the features that can be recognised and attacked by the recipient's immune system. Also, because umbilical cord blood lacks well-developed immune cells, there is less chance that the transplanted cells will attack the recipient's body, a problem called graft-versus-host disease.

Parkinson's disease, birth defects such as cerebral palsy, Alzheimer's disease, and spinal cord injuries. Currently there are three private stem cell banks in South Africa[§] with storage facilities for the cryopreservation (freezing of stem cells in liquid nitrogen) of adult stem cells and cryogenic preservation of umbilical cord stem cells, as well as preservation and storage of eggs and sperm for artificial insemination or other fertility treatments.[6]

Current regulatory framework

The regulatory framework for the use of stem cells for therapeutic or research purposes include the Constitution,[7] the law of informed consent, and ethics and legislation in the form of the Human Tissues Act and the National Health Act.

The Constitution and ethics

In the context of stem cell research and the Constitution, one must have regard to the Bill of Rights, namely:

- The right to equality (section 9)
- The right to human dignity (section 10)
- The right to life (section 11)
- The right to freedom and security of the person, decisions concerning reproduction, security in and control over one's body (section 12)
- The right to privacy (section 14)
- The right to conscience, religion, thought, belief and opinion (section 15)
- The right to access to healthcare services (section 27)
- Section 28 dealing with children's rights.

These rights are not absolute and are subject to the general limitation imposed by section 36 of the Constitution.

With regard to constitutional rights, the issue is whether an embryo has rights which require constitutional protection, such as the right to life and the right to human dignity, or whether the rights of the mother trump those of the embryo (to the extent that they exist). Furthermore, should a person be allowed to reproduce in order to obtain stem cells from one embryo for the therapeutic treatment of other children or for research purposes to advance and develop new treatment?

Legally, an embryo or fetus is regarded as part of the mother and is not an independent bearer of rights.[8] Religious groups would disagree, advocating that life begins at fertilisation and that human embryos are inherently valuable and should not 'voluntarily' be destroyed as they are 'from the moment of union of gametes human subjects with well-defined identities'.[9] These are the arguments that were relied on not so long ago in respect of abortion. The focus should, therefore, be on whether an embryo should be afforded the same legal status as a born human being.

Since South African law does not recognise a fetus as a person, a fetus's right to life is not protected by the Constitution. The mother's right to decisions concerning reproduction, security in and control over one's body, as well as bodily privacy and the right to abort in terms of the Choice on Termination of Pregnancy Act,[10] will take precedence over those of an unborn fetus. The mother should have the choice to have an embryo destroyed should she exercise this right.

The concerns regarding stem cell research of embryos relate to ethical issues, such as at what stage in embryonic development research should be conducted. Should embryos be created solely for research purposes? There is some concern that if stem cell research is allowed, there will be a mass production of human embryos which will require their destruction in order to harvest stem cells, and in the process women as the providers of embryos will be exploited.[11] This must therefore be guarded against.

Human Tissues Act

The Human Tissues Act is not particularly helpful when it comes to the regulation of the use of stem cells. Stem cells can fall into either the definition of 'tissue' defined as any human tissue including any flesh, bone, organ, gland or body fluid or 'blood product' which is defined as any product derived or produced from blood.

Generally, in terms of the Human Tissues Act, no tissue may be removed from a living body for the purposes determined in the Act except in accordance with prescribed conditions and with the written consent of the person from whom the tissue is removed or a guardian in the case of a minor.

In terms of Section 19 of the Human Tissues Act:

> 'Any tissue, blood or gamete removed or withdrawn from the body of a living person shall, subject to the regulations, only be used for medical or dental purposes, including –
>
> (a) In the case of such tissue, the use of transplanting thereof in the body of another living person or for the production of a therapeutic, diagnostic or prophylactic substance ...'

In terms of the current law the use of stem cells harvested from living persons and used for any therapeutic or research purpose with the consent contemplated in the Act is allowed. However, in terms of section 19(c)(iv), removal and use of embryonic and umbilical cord stem cells can only be done with the consent of the Minister of Health. That is in addition to the general requirement of informed consent. Unfortunately, the Human Tissues Act does not deal with issues relating to how stem cell research should be conducted, whether storage of stem cells should be permitted, and the controversial issues surrounding the creation, use and destruction of embryonic stem cells.

Human cloning for therapeutic or research purposes, is expressly prohibited in terms of section 39(A) of the Human Tissues Act which provides that '… no provision of the Act shall be construed as to permit genetic manipulation outside the human body or gametes or thyroids'.

National Health Act

Section 55 of the National Health Act is similar to section 18 of the Human Tissues Act in that it requires written consent of a person from whom the tissue, blood, blood products or gametes are removed for purposes referred to in section 56.

[§]The three private stem cell banks include Lazaron Biotechnologies SA Ltd, which specialises in umbilical cord blood storage and preservation; Netcells Cyrogenics, which specialises in storage and preservation of umbilical cord stem cells, peripheral blood (from blood stream for bone marrow transplants) and reproductive cell banking in the form of storage and preservation of eggs and sperm for future fertility treatments or artificial insemination; and Cyro-Save, which stores its preserved stem cells at its headquarters in Belgium.

Section 56 deals with the use of tissue, blood, blood products or gametes removed or withdrawn from living persons and provides that:

> 'A person may use tissue gametes removed, applied or applied products withdrawn from a living person only for such medical or dental purposes as may be prescribed.
>
> (2)(a) subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in sub-section (1):
>
> (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.
>
> (b) the minister may not authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect for such removal or withdrawal.'

Section 57 prohibits the reproductive cloning of human beings and expressly provides that:

> '(1) A person may not –
>
> … engage in any activity, including nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being.
>
> (2) The minister may, under such conditions as may be prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells.
>
> (4) The minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if –
>
> (a) the applicant undertakes to document the research for record purposes;
>
> (b) prior consent is obtained from the donor of such stem cells or zygotes.'

For purposes of this section, 'reproductive cloning of a human being' means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose and 'therapeutic cloning' means the manipulation of genetic material from either adult zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues.

On 5 January 2007, the Minister of Health published regulations for public comment, regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics.[12] The regulations prescribe useful guidelines regarding the use of stem cells for therapeutic and research purposes. Chapter 1 of the regulations prescribes conditions relating to the harvesting and use of biological material which includes stem cells, chapter 2 deals with research relating to the use of, among others, stem cells and chapter 3 regulates genetic, stem cell registers and research findings which involve long-term storage of stem cells.

On 1 April 2011, further regulations relating to the general control of human bodies, tissue, blood, blood products and gametes were published.[13] Chapter 2 of the regulations which deals with the procurement and use of tissue, blood and gametes from living persons reinforces the requirement that any removal of tissue from a living body must be done with the consent of the person from whom such tissue is removed and in the case of a minor, the legal guardian.

Those regulations are still in their draft form and will be perfected when chapter 8 is enacted. South Africa is, therefore, '*currently operating in a regulatory vacuum in which the rules and guidelines are fragmented.*'[14,15]

The lack of a uniform regulatory framework to regulate the use of stem cells is hindering South Africa's growth in this development of regenerative medicine. There is therefore an urgent need for government to provide a proper regulatory framework in order for private and, in time, public health establishments to advance the use of stem cells in the health industry.

References

1. http://www.religioustolerance.org/res_stem.htm (accessed 10 December 2011).
2. National Health Act (Act No 61 of 2003) (as amended).
3. Human Tissues Act (Act No 65 of 1983) (as amended).
4. http://www.medterms.com/script/main/art.asp?articlekey=10597 (accessed 10 December 2011).
5. http://www.lifecellinternational.com/sources-of-stem cells.aspx (accessed 10 December 2011).
6. Kassah JE. Current state of stem cell research and its application in South Africa, April 6 2011 http://embrybros.wordpress.com/2011/04/06/current-state-of-stem cell-research-and-its-application-in-South-Africa/html (accessed 10 December 2011).
7. Constitution of the Republic of South Africa, 1996.
8. Carstens P, Pearmain D. Foundational Principles of South African Medical Law Durban: LexisNexis: 2007:190-199.
9. http://enwikipedia-org/wiki/stem_cell_controversy (accessed 10 December 2011).
10. Choice on Termination of Pregnancy Act (Act No. 92 of 1996).
11. Schuklenk U, Lott J. Ethics, politics and embryo stem cell research in South Africa. S Afr Med J 2002;92:782-786.
12. Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics (GN R7 of 2007 01 05); and regulations relating to human stem cells (GN R376 in GG 29840 of 2007 05 04) National Health Act (Act No. 61 of 2003) (as amended).
13. Regulations regarding general control of human bodies, tissue, blood, blood products and gametes (GN R268 in GG34159 of 2011 04 01), National Health Act (Act No. 61 of 2003) (as amended).
14. Pepper MS. The stem cell regulatory environment in South Africa – cause for concern. S Afr Med J 2009; 99:505-507.
15. Pepper MS. Cell-based therapy – navigating troubled waters. S Afr Med J 2010;100:286-288.