

**Presentation at the Christians in Pharmacy meeting in London
Saturday 29 October 2016**

THE ETHICS OF STEM THERAPY

1. ETHICAL CONTROVERSIES IN STEM CELL RESEARCH

Embryo: In humans, the embryo is the organism in the early stages of growth and differentiation, the period from fertilization to the beginning of the third month of pregnancy. After that point in time, an **embryo** is called a foetus. The embryo is differentially defined as a foetus at 8 weeks because the structures which will give rise to all major organs are already present. Until birth, the unborn offspring is called the foetus.

Many, but not all, of the ethical problems of human stem cell research relate to the **source** of stem cells. There are three main types of stem cells which are being researched:

I. Embryonic stem (ES) cells

ES cells are obtained from early-stage embryos. This is because early embryos contain embryonic stem cells which could potentially form almost any tissue of the body if they are removed and grown under the right conditions.

- Most human ES cell lines are generated from unused embryos from *in-vitro* fertilisation (IVF) clinics. These embryos were created as part of fertility treatment, but were not needed for a pregnancy, and were donated for research.
- In some cases, embryos can be created specially for stem cell research from donated eggs and sperm, using IVF methods.
- Embryos have also been created specially for stem cell research by activating donated human eggs without the use of sperm (parthenogenesis).

II. Tissue stem cells

They are sometimes less accurately termed ‘adult stem cells’. But the term ‘adult stem cells’ merely denotes that they are not of embryonic origin, not that they come from fully mature adults. Tissue stem cells are found in many organs and tissues in the body, including bone marrow, blood, cornea, retina, intestine, muscle, nervous system, brain, and skin. They are also found in developing organs in the foetus, umbilical cord and placenta. Their role in the body is to replace cells which die throughout life due to wear and tear or injury and disease. For example, stem cells in bone marrow replace blood cells.

They are multipotent: typically only give rise to the cells of the tissue in which they are found. Their capacity to generate other cell types is usually limited.

Tissue stem cells may be derived from foetal tissue. The use of foetal cells raises similar ethical issues as those raised by embryonic stems cells, though this could likely be even more controversial given the later stage of development.

III. Induced pluripotent stem cells

Pluripotent cells: capable of giving rise to all the cell types of a mature organism but not able to support the development of an embryo. Scientists have more recently found another way of producing pluripotent stem cells without using embryos. Some

specialised cells can be ‘reprogrammed’ to become pluripotent so that they lose their specialist functions and behave in virtually the same way as embryonic stem cells. Pluripotent cells generated in this way are called induced pluripotent stem cells (iPS cells).

Summary: In principle, stem cells can be obtained from adults, from umbilical cord blood, from foetal tissue, and from embryonic tissue. *However, it is the generation of human ES cells which has raised the most ethical concerns. The ethical concerns centre on the status of the embryo.*

2. VIEWS OF THE EARLY EMBRYO

There are three classic viewpoints on the early embryo used to provide stem cells:

- The early embryo is merely a collection of a few cells in the earliest stage of human development.
- The embryo, in terms of its moral status, is as much a human being as a new-born baby.
- The human embryo is more than just a collection of cells, but it need not be treated in the same way as we would a baby.

Put another way, a key issue in deciding our view on the use of human embryos is whether we regard the embryo as merely a ‘**thing**’, an **actual person**, or a **potential person**.

Three main views on the moral status of the early human embryo

I. The embryo has no moral status, especially in the early stages

Proponents view the embryo in terms of its composition, properties and functions. In the early stages, a human embryo expresses no discernible bodily characteristics, is not thought to be conscious or feels anything. As it lacks the characteristics and properties that define human being and human personhood, it cannot be regarded as a human person.

Further, at the blastocyte stage, it could split to produce twins, so it cannot yet be said for sure that this is a single individual. It has not yet implanted in the womb. The mother would not even be aware that she is pregnant. It could not survive outside the womb. Therefore, in the earliest stages of development, the embryo has no moral significance.

Consequence of this view:

- Research on early (and later) human embryos is permissible, subject only to the normal ethical constraints of research methodology, including consent.
- Research on early human embryos is desirable. The potential for relieving and treating human suffering must override other concerns.

II. The embryo has the same moral status as a baby

The human embryo is an unborn child. We must not judge the status and value of the embryo by its particular state of development, but by what it will become, namely a human person. From the completion of fertilisation onwards the embryo has the status of the human being which it should become. Other humans do not have the right to destroy it or cause it to be destroyed.

Further, we have a special duty to protect the most vulnerable in our community, and nothing is as vulnerable as an embryo. Society is considered 'civilised' only when it respects the rights and liberties of all human beings, especially the weaker elements.

Consequences of this view:

- No research should be allowed that is not for the benefit of that particular embryo
- The ends, no matter how altruistic, can never justify the means, especially when it leads to taking the life of an embryo, denying it the chance to become a fully developed human.
- Proponents of this view advocate only the use of stem cells derived from tissue stems cells and other non-embryonic stem cells

III. The human embryo has more moral status than a mere collection of cells in the body, but it does not have the same status as a new-born baby

We do not, therefore, need to accord the embryo the same rights as the fully developed person. Despite the respect we accord the embryo, we are also duty bound to pursue the relief of human suffering.

Representative of this view is the position taken by the 1984 Warnock Report on fertility and embryo research. The authors argued that "the embryo of the human species ought to have a special status and that no one should undertake research on human embryos the purposes of which could be achieved by the use of other animals or in some other way".

There are several implications to this view:

- The researcher is obliged to look for alternatives to embryo research, use them where possible, and only use embryos where there is no alternative.
- If an alternative is established, the implication is that human embryo research can no longer be morally justified.
- The research would be for one of an agreed set of significant medical goals, like the treatment of serious disease or crippling injury, and the underlying biological understanding needed to develop such treatments.
- Some areas of research should not be allowed to use human embryos.
- Research should only be allowed up to a certain point in the development of the embryo (see the 14 day rule below).
- There must be some formal system to regulate, control and license research

14 day rule

After what point in the development of an embryo should no research be allowed? The Warnock Committee (1984) recommended 14 days, because at about this time there are several ethically significant biological changes. Shortly after this the 'primitive streak' begins to appear, which will make the three germ layers including the cells that will become the central nervous system, which in turn will lead to consciousness and sensory feeling. After this, twinning is no longer normally possible, so we know that it is indeed one particular individual. Implantation in the womb is normally complete by then.

Consequences of this view:

- There are certain limited circumstances under which research on human embryos might be allowed

- The seriousness of certain medical conditions would justify the use of stem cells derived from embryos.
- The human need is as important as the need to value the embryo
- In practice, this intermediate ethical position tends to justify policies that differ little from policies that assume the embryo has no special moral status.

Using surplus IVF embryo

- Many who might have serious reservations about the idea of using embryos for stem cell research accept it nonetheless where the source is surplus embryos left over from IVF treatments, which would otherwise be destroyed. This is perhaps the most commonly held justification. If these embryos would not now have any chance to develop into babies, because the couple who created them does not wish to attempt further pregnancies, why not use them for potentially very beneficial medical research?
- Those objecting think that to create an embryo just for research treats it purely as an instrument towards an end, inconsistent with its special moral status.

3. PRINCIPLE OF FUNCTIONALITY

One key issue in deciding our view on the status of the human embryo is whether it is a person and how we assign value to that person. The so-called ‘principle of functionality’ often dominates the thinking of those who support research on human embryos. In essence, this principle states that our value as persons is tied up with what we can “do”. ‘Human beings are simply functional, utilitarian beings’ and it is society, not God, which determines the value of human life.

Proponents of this principle argue that the early human embryo does not have any bodily characteristics and is not thought to be conscious. It has none of the abilities which define a person, for example, the ability to relate to other people, to feel, or to communicate. It could do nothing, and cannot survive outside the womb. They draw the conclusion that the embryo, especially in its early stages, is no more than a ‘thing’.

Problems with this view

- The Christian view is that the embryo is God’s created being, known to Him and, therefore, special to Him.
- Every human being has intrinsic value apart from our abilities, simply because we are made in the image of God. Basing our views of what a person is on their abilities has serious implications on the way we value foetuses (in any stage of development), newborn babies, and people with physical and mental disabilities. If human rights and dignity are conditional on the possession of specific capacities, we need to remember we are all liable to lack or lose some of these abilities in the course of our lives! The Christian principle is that we are all of equal value no matter what abilities we have or do not have.
- Although the early embryo lacks a whole range of abilities, it is clearly human and has the potential to acquire a full range of abilities if allowed to implant in a woman’s womb and develop into a baby. The human embryo is dependent, but it is only dependent in the same sense that a newborn child is dependent on its mother to provide nourishment. This is no different to the elderly who need care or the very ill who need intensive medical attention.
- Once the sperm has fertilised the ovum, a new individual has been created. The standard position of both traditional and contemporary embryology is that a

human life begins at fertilisation. The fertilised embryo already has all of the necessary genetic makeup for becoming a fully-developed human being. It is qualitatively human in the sense that its chromosomal makeup is that of a human being. It is not an animal or an inanimate thing.

- The key difference between the small embryo and the slightly larger baby is almost purely one of development. Human embryos are human beings at a very early stage of development.

4. ALTERNATIVE TO USING HUMAN EMBRYOS

It has been argued that ES cells are more versatile than tissue stem cells and could, therefore, be utilised to treat a greater range of diseases. But the argument is countered by the very rapid and significant scientific advances in ethically uncontroversial methods of research using ‘adult’ or non-embryonic stem cells and ‘induced pluripotent’ stem cells (iPS) technology.

If these methods are shown to be viable and safe alternatives to using human embryonic stem cells, is there a moral obligation to abandon embryo stem cell research? The implication is that human embryo research can no longer be morally justified.

5. NEW ETHICAL CHALLENGES IN STEM CELL RESEARCH

a. Creating animal-human mixed (hybrid) cells

The Human Fertilisation and Embryology (HFE) Act (2008) allows hybrid cloned embryos to be created for research, using animal eggs instead of human ones. One particular strand (cytoplasmic hybrids) involves transferring the nuclei of human cells, such as skin cells, into animal eggs from which almost all the genetic information has been removed. Proponents argue that the shortage of donated human eggs was holding up stem cell research and potential treatments. Opponents criticise it on ethical grounds for mixing reproductive cells, and on scientific grounds, in that advances in iPS cells may make this approach to making pluripotent cells largely irrelevant.

b. Creating saviour siblings

The HFE Act 2008 sanctions using pre-implantation genetic diagnosis (PGD) to select from among human embryos ones that are ‘compatible’ with a pre-existing elder sibling. The genetically-compatible embryos are then implanted in the mother’s womb, and the remaining incompatible embryos are destroyed or donated to other women seeking IVF treatment. Once the implanted embryo is born, blood stem cells from the umbilical cord or cells from the cord itself (and possibly other body elements) are harvested and used to treat the ill sibling.

c. Therapeutic cloning

A somatic cell (or body cell), is any cell of a living organism other than the reproductive cells – the egg or sperm. Theoretically, taking the genetic material from a human adult’s cell, placing it inside a human egg and allowing it to grow, could lead to the birth of a human ‘clone’. Proponents are only suggesting the use of cloning techniques to generate stem cells from these specially manipulated embryos.

The UK Government, in 2000, controversially voted to allow the use of somatic cell

nuclear replacement to make ‘cloned’ embryos from which stem cells could be produced. This has led to the concept of ‘therapeutic cloning’, as opposed to ‘reproductive cloning’. However, a created cloned embryo can be used not only for the purposes of research and therapy, but also for reproduction.

d. Deriving sex cells (sperm and eggs) from human embryonic and tissue stem cells

Some research groups have claimed to have made human sperm and egg precursor cells from embryonic or bone marrow stem cells. This could lead to all sorts of ethical sexual issues. For example, it could lead to the possibility of a lesbian couple having their own biological children. The child would not in any way be connected to a father. Other scientists have warned that manipulating stem cells to develop into mature sperm could cause permanent genetic changes in the sperm, risking the creation of deformed babies.

e. Using human embryonic stem cells (or cells derived from them) to test drugs and chemicals for toxicity

Pharmaceutical drugs have to be tested and under new 2007 European Community REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) regulations so do all existing industrial and household chemicals. Toxicity testing is not currently on the list of permitted uses of human embryos under the HFE Act. But having created an embryonic stem cell line, say for Parkinson’s research, can the same cells be used for purposes which would have been refused a licence, like drug screening or toxicology testing?

Opponents argue that that the same limits on what the embryo can be used for must apply also to whatever uses the cells would subsequently be used for. Further, if toxicity testing using animals is unacceptable to many people, how can we then justify such procedures on cells derived from human embryos?

6. OTHER ETHICAL ISSUES OF CONCERN IN STEM CELL RESEARCH

Other ethical issues about stem cells

- Exaggeration and scientific integrity. Both exaggerated claims about the potential of ‘breakthroughs’ in stem cell science, and their objections, can mislead and confuse people.
- Patenting of human stem cell lines. Is this in the public interest?
- Will stem cell treatments be available and affordable for all?
- Will stem cell therapies only be pursued for commercially profitable illnesses?
- Consent. How do we ensure informed consent, impartial counselling, and separation of researchers from any commercial and political interests
- Justice and equity. Are we justified in engaging in very expensive research when so much human suffering can be relieved by channelling a fraction of these resources into tackling widespread and treatable diseases?

7. CONCLUSION

- Knowledge acquired from the natural sciences helps us think through what we should do and be, but it cannot provide answers to our moral questions, nor does it necessarily provide any special expertise for thinking about them (the Witherspoon Council).

- We cannot think about stem cell research simply in terms of the health benefits it might confer. We should also consider how those health benefits will contribute to our flourishing as human being. We should consider how our ethical judgements relating to biomedical research will reflect on and shape our character as persons and as a society (the Witherspoon Council)
- Science cannot simply pursue the acquisition of knowledge without any consideration of the means involved in reaching its desired ends, even if those ends are purportedly altruistic (e.g. finding disease cures). Science **must** operate within ethical boundaries.
- Science must operate within a framework that has boundaries that are not merely the product of social consensus. Otherwise, our system would operate according to little more than a thinly-veiled version of ‘might makes right.’ (Christian Concern)
- Christians must live and make decisions based on the revealed word of God in the Scriptures, even if they are counter-cultural
- ‘For me, stem cells show how important it is to consider what wider human values are affected, as science digs ever deeper into human biology. So that we do not just say “Wow!” but we also ask ourselves, “But what is right?” Dr Donald Bruce, Ethicist

Note: a lot of the statements in this paper are lifted directly from the sources listed in the bibliography, sometimes with minor re-phrasing. No credit is assumed by the author of this short paper for any originality. A glossary of definitions can be obtained from the material produced by Barfoot J et. al. My thanks to the authors below for the excellent material they have produced.

BIBLIOGRAPHY

Barfoot J, Bruce D, Laurie G, Bauer N, Paterson J, Bownes M. (2010). Stem cells – Science and Ethics, 3rd edition, the Biotechnology and Biological Sciences Research Council (BBSRC)

Christian Concern: Protecting the embryo: why it’s essential

Jones P. Therapeutic cloning and stem cells. CMF Files (2000)

The Witherspoon Council on Ethics and the Integrity of Science, ‘Appendix C: Ethical considerations Regarding Stem Cell Research,’

The New Atlantis, 2012; 34: 98-113