THE ROYAL SOCIETY

Stem cell research and therapeutic cloning: an update

Summary

- Degenerative diseases and serious injuries to organs and tissues may be treated through stem cell therapies.
- Research on human embryonic stem cells will be required to investigate all of the potential therapies because other cell types, such as adult stem cells, may not have the same breadth of applications.
- The proposed legislative controls will be sufficient to prevent reproductive cloning (i.e. the cloning of people) while still allowing the development of therapeutic applications of cloning technology.
- The Royal Society believes that the proposed new regulations under the 1990 Human Fertilisation and Embryology Act, which would allow research on human embryonic stem cells, are scientifically necessary to realise fully the potential of stem cell therapies.

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Parliament will be asked shortly to vote on a proposal to allow research on stem cells derived from human embryos to investigate the possibility of new treatments for damage caused by burns, injuries and degenerative diseases such as Parkinson's, multiple sclerosis, cystic fibrosis, muscular dystrophy, diabetes, hepatitis and osteoporosis. This briefing note provides up-to-date scientific information about the significance of the proposed legislation.

The 1990 Human Fertilisation and Embryology Act strictly regulates research on human embryos and prevents embryos beyond day 14 of development from being used. The Act states that scientists must obtain a licence from the Human Fertilisation and Embryology Authority (HFEA) to carry out embryo research before day 14.

Embryos may only be used if they have been produced in the course of *in vitro* fertilisation treatment but are surplus to clinical need or if they have been produced specifically for research. At present, the law allows licences to be granted only for research that is judged to be both necessary and desirable for developing infertility treatments, contraception, or methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, or for understanding the causes of congenital diseases and miscarriages. If the terms of the 1990 Act are extended through affirmative regulations, the HFEA will also be allowed to grant licences for the use of embryos for research into cell-based therapies for diseases and serious injuries.

1 What are stem cells?

These are cells that can replicate themselves and also generate more specialised cell types as they multiply. Stem cells occur at all stages of human development, from embryo to adult, but their versatility and abundance gradually decreases with age. While embryonic stem cells may be able to produce any of the 200 different types of specialised cells that make up the human body, adult stem cells appear to be much less versatile.

2 How might stem cells be used to develop treatments for diseases?

Most of the body's specialised cells cannot be replaced by natural processes if they are seriously damaged or diseased. Although some of these conditions or injuries can be treated through transplantation of entire healthy organs, there is an acute shortage of donors, and xenotransplantation (i.e. the transplantation of organs into humans from other species) carries presently unquantifiable risks that cast serious doubt on its use to make up the shortfall. It may be possible, however, to treat patients by transplanting specialised cells that are grown from stem cells in the laboratory.

3 How will research on stem cells derived from human embryos contribute to the development of these new treatments?

Embryonic stem cells for therapeutic purposes would be derived from embryos that are about one week old, typically measuring less than one-fifth of a millimetre in width and containing about a hundred cells. Embryonic stem cells can be multiplied in the laboratory for many days, or even months, before being induced to form particular types of specialised cells (eg to form muscle, nerve, skin, etc).

The unique potential contribution of human embryonic stem cells to therapies is a product of both their longevity and their capacity to produce a wide range of specialised cells in the laboratory. By contrast, adult stem cells that are grown in the laboratory appear to have much shorter lifespans than embryonic stem cells. This reduces their capacity to form new cell types. Stem cells can also be obtained from aborted fetuses and umbilical cord blood, but it is not clear whether the full range of cell types that are required for treatments could eventually be generated from these sources alone.

4 How might cloning technology be used in the development of stem cell therapies?

If the transplanted cells are grown from stem cells that are not genetically compatible with a patient, the immune system will reject them. Cloning technology could be used to overcome the problems of rejection. If the nucleus of a patient's cell were transplanted into an egg cell that has had its own nucleus removed, it might be possible to generate an early embryo from which stem cells can be extracted. The genetic make-up of these stem cells, from which specialised cells might be produced, would be essentially identical to the patient's cells. As this technique, sometimes called therapeutic cloning, involves the creation of an embryo, it is governed by the 1990 HFE Act, and so requires a licence from the HFEA. Therapeutic cloning would not involve embryos that have developed beyond day 14 of development, and does not require the embryos to be implanted into the womb.

5 Do the recent advances in research on stem cells obtained from sources other than embryos, such as adult tissue, mean that eventually it will be possible to use these cells for all the purposes that have been contemplated for human embryonic stem cells?

Stem cells are found in some adult tissues, and these may be used as sources for specific types of specialised cells. But there are many doubts about whether adult stem cells will prove to be as versatile as embryonic stem cells, which have the potential to give rise to all cell types of the adult body.

Eventually it may be possible to re-programme cells to reverse their specialisation so that they revert to being stem cells, or to force specialised cells to replicate themselves. However, much further research on stem cells and cloning technology would be needed to decide whether these are realistic possibilities.

6 Could cells from non-embryonic sources ever render research on human embryonic stem cells unnecessary for the development of cell-based therapies?

At some point, research on embryonic stem cells might no longer offer any advantages over work with stem cells from sources such as adult tissue. But much more basic research is required to find out how stem cells from non-embryonic sources can be extracted, kept alive in the laboratory, multiplied for extended periods of time, and directed to form specific types of specialised cells. The progress of this research would be facilitated by the study of embryonic stem cells.

Adult stem cells are typically present only in small numbers and replicate at relatively low rates because they are self-programmed to maintain the function of fully-developed organs and tissues. Embryonic and fetal stem cells are much more prolific and versatile and are therefore more likely to generate sufficient tissue to replace severely damaged parts of the body. Moreover, scientists already have knowledge and experience of growing such stem cells in the laboratory.

7 If research on non-embryonic sources of stem cells could reach a point where work on human embryonic stem cells would be unnecessary, how soon would it be reached?

It is difficult to predict the pace of future research. Nonetheless, it seems very unlikely that we will be able to answer within the next 10 years all of the outstanding questions about stem cells, and it might be several decades before we achieve a full understanding of how the specialised state of cells is achieved and maintained.

Despite the exciting recent reports about the potential of adult stem cells in mice, we are still at a very early stage in the research. It is possible that we will never be able to overcome all of the hurdles blocking the path to their use therapeutically. Stem cells derived from umbilical cord blood and adult bone marrow have already been used therapeutically, but their application has been, so far, limited to treating diseases of the blood system.

Both embryonic and adult stem cells have advantages and shortcomings, and it is not possible at present to say which will ultimately prove to be of greater value therapeutically. This can only be decided by allowing research that will enable a critical evaluation of the potential of stem cells from both sources.

8 Could research on human embryonic stem cells provide us with effective therapies more quickly? If so, how much quicker?

Again, it is difficult to make predictions. Our understanding of embryonic stem cells is more advanced than it is for most types of adult stem cells. A great deal of research has been carried out on embryonic stem cells from mice, and these results may allow work on human stem cells to progress comparatively rapidly. Therefore, initial therapeutic applications are likely to be based on transplants of embryonic and fetal stem cells that are not genetically matched to the patient and must be accompanied by the use of drugs that suppress the response of the body's immune system to the foreign tissue.

Advances in cloning technology that would allow the creation of embryonic stem cells that are compatible with patients' immune systems would take longer to develop. However, these cells would overcome the rejection problems that frequently cause grafts of foreign tissue to fail. It is therefore important to allow research into this technology to proceed in order to improve its efficiency and to allow embryonic stem cells that are generated in this way to be tested for their capacity to give rise to a wide spectrum of normal cell types that are suitable for therapeutic uses.

9 Given the complex ethical and legal issues surrounding the use of human embryos and the advances in research on non-embryonic sources of stem cells, is it appropriate and desirable at this stage to introduce affirmative regulations under the 1990 Human Fertilisation and Embryology Act to allow the use of human embryos for this research?

At present, more research is required on stem cells derived from the full range of possible sources. The length of time that it takes to develop therapies will depend on how rapidly progress is made in understanding each of the different stem cell types, and so it is desirable that research on human embryos is allowed for this purpose. It is quite likely that research on embryonic stem cells will lead to more rapid advances in the understanding of adult stem cells.

10 Will patients benefit any sooner from the development of potential cell-based therapies if UK legislation allows this research on embryos, given that UK researchers would still be allowed to import human embryonic stem cells from abroad?

UK scientists are at the very forefront of research into stem cell therapies, and have a strong international reputation for the study of mammalian developmental biology in general. The UK has adopted a pioneering and internationally-respected stance on the regulation of research on human embryos.

If scientists are unable to obtain stem cells directly from embryos in the UK, they will need to seek other sources, such as commercial research organisations in the United States or elsewhere. This may prove more expensive and time-consuming, and could hinder the progress of their studies. Some British researchers might consequently decide to move overseas to carry out their research.

The UK could be regarded as operating double standards if it prevented embryos from being used in this country to obtain stem cells, but allowed the import of embryonic stem cells from abroad. Similarly, if therapeutic cloning technology is developed abroad, it would be hard to deny British patients the opportunity to benefit from it.

11 Will research conducted outside the UK generate results of comparable quality to that carried out here?

Scientific research is an international enterprise. However, much of the work on stem cells outside the UK has been carried out in the private sector and has not been published. Most of the high quality research by UK scientists has been published so that the acquired knowledge can be shared. It is important that research in this field is carried out in the public domain so that it can be subjected to proper scrutiny. Appropriate legislation and public funding are needed if this work is to be carried out successfully in the UK.

12. If research into the use of cloning technology to develop stem cell therapies is allowed in the UK, will this make human reproductive cloning more likely?

Many years of research would be needed before it might prove possible to safely use cloning technology to develop cell-based therapies. Scientists would require a licence from the HFEA if affirmative regulations are made under the 1990 Human Fertilisation and Embryology Act to allow this research. As the HFEA has indicated that it would not grant a licence for attempts to implant a cloned embryo into the womb so that it could develop into a fetus, human reproductive cloning could not be carried out. The UK Government, in its response to the Donaldson report, has indicated its intention to outlaw explicitly human reproductive cloning, in line with other countries, such that implantation of a cloned embryo into the womb would be illegal. The potential of a cloned human embryo to develop into a fetus will therefore remain unknown.

This briefing note has been endorsed by the Council of the Royal Society. It was prepared by a working group chaired by Professor Richard Gardner (Dept of Zoology, University of Oxford), and comprising Dr Maeve Caldwell (MRC Centre for Brain Repair, Cambridge), Professor Christopher Graham (Dept of Zoology, University of Oxford), Sir John Gurdon (Wellcome CRC Institute, Cambridge), Sir Aaron Klug (MRC Laboratory of Molecular Biology, Cambridge, and President, Royal Society), Dr Robin Lovell-Badge (National Institute for Medical Research, Mill Hill, London), Dr Anne McLaren (Wellcome CRC Institute, Cambridge, and member of the Human Fertilisation and Embryology Authority), Dr Robert Moor (Babraham Institute, Cambridge), Dr Austin Smith (Centre for Genome Research, University of Edinburgh), and Professor Azim Surani (Wellcome CRC Institute, Cambridge), with support from Ms Kirsty Brown, Ms Sarah Teather and Mr Bob Ward (Secretariat, Royal Society).

The following journal papers have been reviewed by the working group during the preparation of the briefing note:

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Other Royal Society science policy documents

***** The full text, or summary, of these reports can be found on the Royal Society's web page **www.royalsoc.ac.uk**

The role of the Renewables Directive in meeting Kyoto targets (12 page document 11/00, October 2000 ISBN 00 85403 5486)

Developing a National strategy for science (8 page document 10/00, July 2000 ISBN 0 85403 5451)*

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Guidelines on the use of scientific advice in policy making (May 2000)

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Nuclear Energy - The Future Climate - Summary (8 pages 11/99, June 1999)*

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Review of data on possible toxicity of GM potatoes (Royal Society statement 9/99, June 1999)*

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Devolution and science (14 page report by a Joint Working Group of the Royal Society of London and the Royal Society of Edinburgh, statement 5/99, April 1999)*

The teaching profession (6 page statement 4/99, April 1999)*

Regulation of biotechnology in the UK (Royal Society response to the Government's consultation exercise, 4 page statement 3/99, February 1999)*

Science and the revision of the National Curriculum (3 page statement 1/99, January 1999)*

Current issues in the scientific, technical and medical information system (report of a workshop held on 21 September 1998 and sponsored by the Association of Learned and Professional Society Publishers, the British Library, Blackwell Science Ltd and the Royal Society, 3 page report, December 1998)*

Use of a policy factor in research funding (response to HEFCE consultation document, 2 page statement 5/98, December 1998)*

Innovating for the future: Investing in R&D (response to the Department of Trade and Industry and the Treasury joint consultation paper, November 1998)*

Foresight (Royal Society response to the Office of Science and Technology Foresight consultation document, 4 page statement 4/98, October 1998)*

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Policy on holding international meetings in the UK (June 1998)*

Cloning Issues in Reproduction, Science and Medicine (response to the HGAC/HFEA consultation document, May 1998)

Mathematics Education Pre-19 (May 1998)*
Response to Qualifications & Curriculum Authority consultation on proposals to permit the wider use of work-related learning at Key Stage 4 (letter from Chairman of Education Committee, April 1998)*

Response to Teacher Training Agency consultation on proposed initial teacher training national curricula (letter from Chairman of Education Committee, April 1998)*

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Science Teaching Resources: 11-16 Year Olds (October 1997; ISBN 0 85403 5125)*

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The Royal Society

The Royal Society is the world's oldest scientific academy in continuous existence, having been at the forefront of enquiry and discovery since its foundation in 1660. The backbone of the Society is its Fellowship of the most eminent scientists of the day elected by peer review for life and entitled to use FRS after their name. There are currently more than 65 Nobel Laureates amongst the Society's approximately 1300 Fellows and Foreign Members. Throughout its history, the Society has promoted excellence in science through its Fellowship, which has included Isaac Newton, Charles Darwin, Ernest Rutherford, Albert Einstein, Dorothy Hodgkin, Francis Crick, James Watson and Stephen Hawking.

The Society is independent of government, as it has been throughout its existence, by virtue of its Royal Charters. In 1663, 'The Royal Society of London for the Improvement of Natural Knowledge' was granted its Arms and adopted the motto *Nullius in verba*, an expression of its enduring commitment to empirical evidence as the basis of knowledge about the natural world.

A Council of 21 Fellows, headed by a President and four Officers, governs the Society. On 30 November 2000, Sir Aaron Klug, OM, awarded the Nobel Prize for Chemistry in 1982, is succeeded as President by Sir Robert May, AC, winner of the Craaford Prize in 1996. The Executive Secretary, Stephen Cox, CVO, heads the Society's permanent staff.

Scholarship has always been at the heart of the Society's activities as a learned body. It publishes five internationally respected peer-reviewed journals, including *Philosophical Transactions of the Royal Society*, the world's oldest title, which first appeared in 1665. Since 1731, the Society has rewarded outstanding achievement through its medals and prizes, and now makes 17 awards each year. The Society also hosts conferences, lectures and discussion meetings for a wide variety of audiences, and houses one of the world's most important collections of 17th and18th century scientific journals and books in its library.

As a funding agency, the Society supports more than 380 post-doctoral fellowships and 18 professorships. It also provides grants for more than 3000 scientists from the UK and abroad to undertake research and participate in visits, projects and conferences. These are complemented by the Society's science policy and communication activities.

As the UK's independent national academy, the Society represents the British scientific community within Britain and in relations with individuals and groups of scientists throughout the world.

The Society is a registered charity and has an endowment from which it runs much of its work. It receives money each year as a parliamentary grant in aid to support specific activities.

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