

Stem cells and Therapeutic Cloning

Professor Derek Burke

Stem cells are pluripotential cells which means that is they have the capacity to develop into any of the numerous differentiated cell types that make up the body. Early embryonic cells are pluripotent and a limited number of stem cells are also found in the adult, in bone marrow for instance.

There is an important distinction to be made between therapeutic cloning and reproductive cloning. Reproductive cloning would be exactly like Dolly; it would involve the creation of a cloned embryo which was then implanted in a womb to develop to term and the birth of a clone. (see previous paper)

On the other hand, therapeutic cloning involves the use of undifferentiated pluripotent cells to repair damaged tissue, such as found after stroke, and in Parkinson's disease, spinal cord injury etc. There is evidence for the effectiveness of therapeutic cloning as shown by work involving the introduction of stem cells into the brain of patients suffering from Parkinson's disease, when the cells which have been added differentiate to form nerve cells which can in turn then lead to recovery of the lost function.

In the US, foetal human cells have been similarly used though recent reports indicate that the results so far are disappointing. However apart from the ethical problems associated with the use of foetal cells in this way, there are simply not enough cells available for it to be an effective treatment, since it needs the cells from three foetuses to treat one patient.

There are several problems with therapeutic cloning:

- It is difficult to get enough cells, so it is important to be able to grow them in vitro,
- There is always the possibility of transformation to form tumour cells in this process,
- There is the problem of immunological rejection. This could be overcome if it were possible to use the patient's own cells but we do not know how to reverse the process of differentiation to enable this. The way round this is by using nuclear replacement, in which a donor nucleus from the patient is fused with a pluripotent stem cell cytoplasm, but this raises other ethical and practical problems.

There has been much debate about whether adult stem cells can be used; that is whether the few stem cells that are found in adults - in the bone marrow for example - can be induced to revert to cells which can differentiate to form cells other than cells of the circulation, their normal role. The overwhelming balance of scientific opinion is that we must be very cautious about the claims to be able to use adult cells, although further research is needed.

Very recently, there has been a claim from scientists working in San Francisco that the stem cells found in the blood of umbilical cords could be used to repair the brain damage suffered by stroke victims. The treatment has been tested on rats with encouraging results and they claim that it could be in human trials within a couple of years. Obtaining stem cells from umbilical cords is far less controversial than sourcing them from embryos (as many scientists would like to do).

If the new research, announced at a recent annual meeting of the American Association for the Advancement of Science (AAAS), lives up to its potential, "banking" of cords at birth could become a common practice; at the moment, virtually all cords are discarded. However, in order to allow cloning for personal use this would mean running a bank for every individual all their lives, an expensive process obviously only available to the rich.

The ethical issues surrounding therapeutic cloning are similar in some ways to the abortion debate; that is when does personhood start? Is the newly fertilised egg a fully formed person or does personhood develop during development of the embryo, which is my own view as an Anglican. If you believe the former - and it is the view of many Roman Catholics - then stem cells work is likely to be out of bounds. We therefore have to decide whether such work is right, wrong or permissible under certain specified circumstances. So 'consequentialist ethics' (if it is useful it must be done) has to be balanced against more fundamental moral issues. Christians agree that:

- Reproductive cloning is not an option,
- We should avoid the instrumentalisation of humans

But how do we balance likely needs against such basic concerns? EU countries are taking different positions - contrast Germany, where all such work with human embryos has been banned, with the UK, where it is permitted under certain circumstances. The US is different again, for it is not permitted there if the work is being supported by Federal funds but there is no restriction if private money is used.

If any sort of cloning is permitted under certain circumstances then there has to be regulation, and such regulation must not only be concerned with what is safe but what is acceptable ethically and socially. So Government Ministers in the UK need a mixture of different sorts of advice: technical - both medical and scientific - and also social and ethical. This is the responsibility of the Human Genetics Commission (HGC), which took over in 1999 the functions of several other somewhat overlapping committees. Its function is to give advice to Ministers in three main areas:

- a) The advisory framework - overlaps, gaps etc.,
- b) Managing change and especially its effect on the NHS, and
- c) Social and ethical issues.

There is also a statutory body, the Human Fertilisation and Embryology Authority (HFEA), which was set up by Parliament in 1990 as a result of the Warnock Report of 1984. Legislation laid out five grounds on which experiments with human embryos up to 14 days after fertilisation could be carried out. Experiments, which are assessed on a case-by-case basis, must be for research investigating therapies for alleviation of infertility, investigation of congenital abnormalities, causes of miscarriage, new approaches to infertility and pre-implantation detection of genetic diseases.

Membership is wide-ranging with 3 lawyers, 3 broadcasters, a bishop and a psychologist plus professionals in the field. About 10% applications have been rejected including sex selection. It should be noted that no change in the law is needed to allow researchers to clone embryos; however the HFEA has declared that it would not approve such applications.

There have been a number of reports on the permissibility of stem cell therapy in the UK. On January 29th 1998, the HGC and the HFEA issued a consultation paper and the result was reported in December 1998. It was in favour of proceeding with therapeutic cloning. The Government then asked the Chief Medical Officer to produce a second report with a committee that included a lawyer, an ethicist and a cleric. 1000 persons responded to the consultation and the final report (The Donaldson Report 2000) also recommended proceeding, but with safeguards.

Meantime the Nuffield Council for Bioethics had produced a Report which concluded that there were no new ethical issues if the research was done with spare embryos, but that there were no compelling reasons to allow additional embryos to be created merely to increase the number of embryos available.

Nobody has recommended making new embryos for stem cell research while there are spare (including frozen) ones available - the only exception would be making embryos by somatic cell nuclear transfer, to evade graft rejection, since of course these are not available otherwise. And of course, parental consent would be necessary.

There have recently been debates in both Houses of Parliament. A debate on the 15th December 2000, for 4 hours, continuing on the 19th for a further 3.5 hours, resulted in a vote by 366 to 174 in favour of approving new regulations which permitted therapeutic cloning on three grounds:

- To increase knowledge of embryos.
- Research to increase knowledge about serious disease.
- Research to be used to develop treatments for disease but not treatment itself.

These regulations were approved in the Lords after a 7-hour debate on January 22nd 2001 by 212 to 92. The Churches came very late into the debate, eleven leaders, including the Archbishops of Canterbury and York, arguing that the issue should be referred to a Select Committee. In the event the Government agreed to:

- Set up a Select Committee to 'report on the issues connected with human cloning and stem cell research', and
- Review the regulations following the Report of that Select Committee,*
- To introduce legislation to prohibit reproductive cloning.

(*this Committee is currently collecting information and opinions)

That is the current position. Perhaps the major strands are:

- An established medical case for therapy,
- A history, going back to the Warnock Report of 1984, of some experimentation in this area,
- A broad acceptance by society at large that experiments with human embryos which are for the good of patients are permissible up to 14 days after fertilisation, and
- A wide-ranging debate, whose outcome however was not unanimous, in society and a free Parliamentary vote.

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