Stem cell therapy: the ethical issues
a discussion paper

Preface

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“There are two parts to the human dilemma. One is the belief that the end justifies the means. That push-button philosophy, that deliberate deafness to suffering [...]. The other is the betrayal of the human spirit: the assertion of dogma that closes the mind.”

Jacob Bronowski 1973

In his beautifully written history of science, *The Ascent of Man*, Jacob Bronowski tells a story about science that is also a story about civilisation. This is not because he confuses scientific advances with a one-dimensional concept of social progress. It is because he never seize to grapple with a bigger question: the question of values. Which values speak out of scientific projects or insights? Which values do we need to live together in a civilised way? Which values should scientists pursue?

Hard questions. Questions that need to be addressed in the debates about human embryology and genetics. The Nuffield Council on Bioethics set out to tackle some of them in their discussion paper on stem cell treatment published in April 2000. Looking back at the report now, it seems to come from a time of innocence. And a certain naiveté seems to speak out of its discussions.

**The discussion paper and its aftermath**

Just a quick reminder of what happened since the publication of the paper: An interim version of the Nuffield recommendations was sent to the Chief Medical Officer’s Advisory Body which investigated stem cell and cloning issues. The CMO’s conclusions in many ways resonated with the Nuffield ones. Following the CMO’s lead, the Government finally introduced secondary legislation late in 2000. The Government’s regulations extended the parameters of embryo research to include research into serious diseases.

What the Government (again following Nuffield and the CMO’s report) did not do was to address a question that subsequently lead to a judicial review, a moral panic, some ‘emergency’ legislation and a successful Government appeal: the Government did not seriously ask whether it was within the Human Fertilisation and Embryology Authority’s remit to regulate the use of embryos that were created by other means than through fertilisation.

At this point it might be necessary to briefly explain the technical basis of stem cell treatment. Stem cells can be derived from human embryos that are a few days old, aborted human foetuses, umbilical cord blood or some types of adult human tissue (for example bone marrow). Because of their unique capacities, stem cells can be made to grow into different types of tissue – blood, nerve cells or heart muscle. It is hoped that one day these cells and the tissues derived from them could be used for treating diseases like Alzheimer’s or Parkinson’s.

Transplanting tissue into a patient’s body always brings with it the problem of immune rejection. And this is where the idea of cloning, here in the form of cell-nuclear-replacement, comes into the equation – and adds to the controversial nature of stem cell research. In order to overcome a possible immune rejection, through cell-nuclear-replacement stem cells are created that contain the genetic information of the patient. This technique is often – and rather hopefully - called therapeutic cloning.

Although this process might sound straightforward enough, it is riddled with difficulties and limitations on a technical level. It seems that stem cells at times differentiate into unwanted cell types and that they might lead to uncontrollable processes in the patient’s body after transplantation. But possibly even more relevant are the legal and social problems
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surrounding the technology of cell nuclear replacement. Crucially, the embryo stem cells created from an egg and the cell-nucleus of an adult donor have not been created through fertilisation. The word ‘fertilisation’, however, features in the legal definition of ‘embryo’ in the Human Fertilisation and Embryology Act 1990.

It is this problem that informed the legal challenge of the newly passed regulations in 2001. The Pro-Life Alliance argued, and the High Court initially agreed that embryos created through cell-nuclear-replacement were not regulated by the 1990 Act because their creation did not involve fertilisation. This in turn led to fears that the Act could not be used to prevent human reproductive cloning, i.e. the creation of a cloned person.

Many readers will remember the debates that ensued in the last months of 2001. For a while it seemed that the births of cloned babies in the UK were imminent. The flames were fanned by Dr Antinori, who threatened to jump onto the next plane to Britain where many desperate women were apparently awaiting to be impregnated with their own or their partners’ clones. Legislation criminalising the implantation of embryos created by cell-nuclear-transfer was rushed through Parliament at an unprecedented speed.

But the legal uncertainty surrounding embryos created without fertilisation remained until the Government finally won its appeal against the previous High Court decision in January 2002. The Court of Appeal decided that the legal definition of embryos had to be read in a more generous, less literal way. It was to include embryos created by cell-nuclear-transfer.

In the remaining half of this short introduction I want to address two questions:

• Is it significant that the Nuffield Report on Stem Cells (like the CMO’s Report, like the Government) did not pick up on the possibility of this legal challenge and the resulting controversies, or that it did not seem to take this possibility very seriously?

• Is the regulatory framework as it now stands, after the successful Government appeal, sufficient to keep track of new scientific developments?

Who is afraid of the ‘big questions’?

The Nuffield Council on Bioethics explicitly states in its terms of reference that it aims to ‘respond to, and to anticipate, public concern’. How come it did not anticipate or respond to the concerns that surfaced so forcefully after the HFE (Research Purposes) Regulations were passed? Similarly, the Department of Health dismissed as irrelevant the concerns about the statutory definition of ‘embryo’ whenever they surfaced in parliamentary debates.

Thinking back to the time when the regulations were initially debated it seems to me that those of us who wanted stem cell research to go ahead (and we are a big majority) tried to avoid at almost all costs to get into the well-rehearsed debates about the moral status of the embryo. We politicians have been having these debates for years, if not decades, whenever it comes to discussing abortion or embryo research (and recently even contraception, as the Pro-Life Alliance mounted a legal challenge against the so-called ‘morning after pill’).

It is understandable that some of us have tired from repeating the same arguments over and over again. We will not convince the so-called pro-lifers, and they won’t convince us, so what is the point in continuing down this line? I am not advocating never-ending ritualised exchanges about whether very early embryos should afford the same legal protection as born people. However, we should not be afraid of confronting the small but vocal so-called pro-life lobby. The majority of citizens and the laws of this country are on our side: Very early embryos are not in law considered to have the same status as born people, otherwise
we could not have any abortions, we could not allow the use of the contraceptive pill or coil or of emergency contraception.

What I am warning against is a different tendency: in our desire to avoid the boring old show of moral outrage by the pro-lifers I sometimes think we tend to dodge the wider and fundamental implications of the question we are addressing. Attempting to leave the Pandora’s box of ‘right-to-life’ unopened, we ignore the fact that there are real concerns, real disagreements about values, real political tensions.

Let’s go back to the concrete example of our stem-cell debates and of the Nuffield paper. It seems to me that the real concerns people have about the use of embryos for research, or about cell-nuclear replacement are not so much about the abstract and rather philosophical question ‘when does life begin?’, but about the real use of embryos or cloning in the world they live in. And the world we live in is characterised, for example, by the market.

Fertility services in the UK and elsewhere are mainly provided by private clinics. Patients are often not ‘prescribed’ services by a responsible (and tight-fisted) doctor; they are consumers. They shop around. This also becomes increasingly the case for other medical services and treatments (for example genetic testing). When discussing the ethics of stem cell research we have to acknowledge that this is the world in which it will take place. Market forces tend to push the limits; they tend to erode taboos, unless they are properly regulated. We can thus be sure that there will be a mad, ambitious or greedy enough doctor somewhere out there who will attempt to sell some pre-mature, over-hyped and often dangerous medical gimmick like reproductive cloning to some well-off consumers. The same applies to useless genetic tests or untested therapies.

Ethics are thus not primarily about the abstract question of the beginning of life or the status of an egg-cell; real-life ethics have to address the question of how a new technology, a new scientific idea will be played out in the real world. Ethical decisions have to tackle head-on the concerns that are triggered not by ‘pure science’ or ‘pure ethics’, but by the interface of commercial medicine, consumer demand, an under-resourced NHS, political controversy and so-on.

Ethical questions can simply not be separated out from questions of regulation, as it is the perceived lack of regulation that triggers many public concerns. And robust regulation has to acknowledge the reality of stem-cell research, its institutional and commercial context. Taking ethics and regulation seriously also means that we don’t need to agree with the views of the anti-research minority, but that we have to listen to the points they raise. We have to properly subject our laws and regulations to a critical reading through their eyes.

And this is where we all failed two years ago. Because we (rightly) disagree with their conclusions we failed to listen to their analysis of the law. However, their ‘hostile’ reading of the HFE Act convinced a High Court judge. The Court of Appeal rescued the Government from further political disaster, but we must all agree that trust in the 1990 legislation, the HFE Authority and stem cells research were damaged in the process. So what can we learn from last year’s debacle?

The current regulatory framework

The stem cell drama should teach us at least one lesson: medical science will move into directions that have not been anticipated by the lawmakers in 1990. Stimulating an egg-cell to develop like an embryo without fertilisation was not explicitly included in the 1990 Act. Thanks to the decision of the Appeal Court it is now covered by the Act. But what about other ways of creating embryonic tissue? What if it is possible to create embryos or stem...
cells out of any cell in the body? What if it becomes scientifically useful to create human-animal hybrid cells or tissues? Who looks after stem-cell lines once they have been created? Is it enough to have a code of conduct from the Medical Research Council? Will this be effective in countering the fears triggered by weak regulation? Don’t we need an independent, publicly accountable body that also has some so-called ‘lay’ members to deal with these questions?

At the moment stem cell lines, once they are created, fall outside the remit of the HFE Authority. The Authority does not seem to have a huge appetite for taking on yet another complicated and labour-intensive chore like the licensing of stem cell banks and treatments. But despite its limitations I believe that the principles of the HFE Authority’s work are still viable: it works within a broad framework that has been laid down by Parliament. But it can react flexibly to new developments. It - ideally - does two major jobs: Firstly, it regulates the day-to-day work of laboratories and researchers, providing quality control and assurance. Secondly, it should keep an open mind for future trends in research involving human embryos, gametes and stem cells.

To me it becomes increasingly clear that the remit of the HFE Authority needs to be radically extended: the boundaries drawn between genetics and embryology, between fertility and other treatments, become increasingly blurred. The limits of the Authority’s work thus become increasingly meaningless. What we need is an Authority dealing with human embryology and genetics, which licenses techniques and laboratories. It needs to follow closely what happens on the ground and at the same time keep an eye on the horizon of scientific and medical imagination.

This is a tough call and it requires resources and staff. The HFE Authority which has been created in 1990 does not have enough of either. Radically extending and reconfiguring the regulatory framework will also necessitate primary legislation. So the HFE Authority is not the only one who needs to be brave: we politicians need to brace ourselves and must pro-actively pursue legislative solutions for the area of human embryos and genetics.

This means in all likelihood that we have to listen yet again to the moral outrage of the minority who thinks that the simplistic insistence on the equal status of a fertilised egg and a born person can be the solution to real life’s real moral and political dilemmas. But they know as well as the rest of us that they will not successfully impose their views on the complexities of political, scientific and reproductive decision-making in the real world. And it must be those complexities that inform our politics, our science and our ethics.

Returning to the introductory quote from Jacob Bronowski, it turns out that we need to acknowledge the complexities of stem cell research and treatment in order to steer through the ‘human dilemma’. We cannot dissolve ethics into pragmatic, utilitarian calculations of costs and benefits and ignore the human consequences of our doing. We must not fall into the trap of simply asserting dogmas, be they based on the belief in God’s will or in eternal scientific progress.

Let the debate between scientists, doctors, patients, politicians and tax-payers about a better framework of regulation for human genetics and embryology begin. May the Nuffield Council on Bioethics play its part.