



Workshop:

Ethical aspects of stem cell repositories and stem cell databases  
Brussels, 17 February 2005

### **ETHICAL PROBLEMS RAISED BY STEM CELL REPOSITORIES AND DATABANKS: Sören Holm**

There are specific ethical problems concerning stem cell banks. The first question relates to derivation of stem cells, since that involves the issues of the status of the embryo, therapeutic cloning, the sources of gametes, the funding of research. The second question is whether and to what degree donors should have the right to control the future of stem cell lines derived from their cells, as well as to what degree they should have the right to economic benefits. And should we consider that the donors' informed consent will give the answer to those questions – actions are acceptable as long as there is informed consent.

Are there situations where it is reasonable to give donors control over the use of the stem cell line derived from their embryos/gametes? How much is it reasonable? The current standard answer seems to be “No”, but is this standard reasonable?

*The first scenario.* For example, “my” stem cell line is very easy to use in pulmonary toxicology screening (to form bronchial epithelia) and therefore becomes the *de facto* standard in pulmonary toxicology screening. This includes significant use of this stem cell line by tobacco industry. Why should I not be able to stop this use, if I am against smoking? I do not want my cell line to be used for this purpose. I am content if GlaxoSmithKline uses it to test inhalers, but I am against its use by tobacco industry. Is there a reason for which I should not be able to stop it? This case does not involve human therapy and by stopping the use of my stem cell line, I will not deprive Parkinson's patients from therapy. I just wish to stop the industrial use of tobacco products.

*The second scenario.* There are at least 4 ways in which embryonic stem cells could theoretically be returned to reproductive circulation: reproductive cloning, creation of haploid gamete-like cells, tetraploid complementation and direct induction of embryo formation. For example, reproductive cloning is prohibited in Europe, but not universally! Is it then unreasonable to give donors the right to control any reproductive use of their stem cell line? And does it matter whether the cell line is derived from a “standard” embryo, or the

one created by somatic cell nuclear replacement (i.e. cloning) technique? I want to control my own reproduction; I have my freedom not to reproduce.

These above-mentioned scenarios are the situations where it is difficult to find arguments for not letting donors have control over their cells.

Another question is whether there should be an economic benefit to the donors? The EU Directive as well as the Oviedo convention state that there should be no benefit for the donor. The arguments against economic benefit for the donors are as follows:

- Payment for human tissues is against human dignity: there is no payment for human tissue because there is no property in human body;
- Contribution of the donor cannot be quantified precisely and it is also not unique – we could just as well have had another donor. It is not their unique contribution, it is just a contribution;
- By introducing payment for donors we might also risk to increase the possibility of coercion;
- Payments would undermine altruism;
- Non-payment is a standard practice in biobanking.

However, there are arguments in favour of economic benefit to the donors:

- Stem cell banks are not standard biobanks. They do not keep the samples from 50000 citizens collected for epidemiological research. They have much fewer donors, which are usually fully traceable, and some cell lines may actually become very valuable in the future;
- Precise value of contribution of others is also imprecisely quantifiable, not just the contribution of tissue or cell donors;
- The financial benefit to the donors could be conceptualised as compensation for future genetic testing and access to health information, and not the compensation for the provided tissue or cells. The EU Directive requires that there should be no payment for human tissue. But shouldn't people be compensated for their contribution, if they sign up for being traceable? Maybe that is what they would be paid for – not for their sample, but for being traceable;
- If there is no upfront payment there is little risk of coercion;
- We should not assume that it is only donors who should be altruistic, when everyone else can be paid. It only makes life easier for the researchers if they do not pay the donors. The main reasons not to institute economic benefits to donors seem to be purely pragmatic and to the benefit of researchers.

Having considered all of these arguments, is the informed consent a solution? Can we say that if the donor has consented not to get any benefits, so it is OK not to give him/her any benefits? Similarly, if the donor has consented not to have any future control over “his” or “her” cell line, it is acceptable not to give him/her any control over the cell line? No, not really because of the following three reasons:

- 1) Unless the donor knows what their stem cell lines might be used for, their consent is of questionable validity. For example, for embryo donors it is not mentioned that someone in the future might use the donated embryo to create a child. When you do not know what your samples are going to be used for – is your consent valid? Does a truly

informed consent then really exist? There are a number of important facts about possible future use of stem cell lines. I donate whatever I donate for what I believe will be for medical research, but medical research is a very elastic term. Will it be sufficient to be sure that the material will not be used outside medical research? Is the concept too vague to ensure truly informed consent?

- 2) Consenting away economic benefits may be stretching the concept of consent beyond its limits. For example, should payments for donors be a standard or a recommended practice? It can be argued whether Mr Moore should have been paid and should have had a share in the researchers' patent money. In the Moore case it was decided that property could not extend to cells and tissues.
- 3) Even if we believe it should be possible to consent away rights, it is still unclear whether it should be standard or recommended practice.

It seems that consent is overloaded and we seek people to consent to more and more things. Some of them are areas where we would normally think that obtaining consent would not be the way to handle the issue. Splitting into consent form and data protection form does not really help the problem.

There is always a theoretical a risk of leakage of stem cell lines. Can we assume that they will not "leak" out? Can we assume that they will not be used in ways contrary to agreements between banks and researchers? Can we assume that they will not find their way to researchers without an agreement with the bank? This partly depends on how strongly the banks and those who derive the stem cell lines will defend their intellectual property rights. Giving donors control of their tissues and cells will not solve the leakage problem. But we cannot say that it will never happen because it is prohibited. Reproductive cloning is prohibited, but is it never going to happen? Yes, we as researchers do control the use of stem cell lines, but not absolutely – this we must make clear to the donors.