



Workshop:

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

HOW TO FIND SOLUTIONS: Anne McLaren

The way to find a solution to the problems posed above is to get a mixed lot of people like us to sit around the table and talk about the problems. Solutions may involve successive approximations and compromises. It is very important to use the same terms for the same things, and to remember that solutions are only solutions in particular contexts.

Regarding databases and registries, it is important to solve the data protection issues. It is important to guarantee the protection of personal data, the confidentiality of genetic information, the regulations to guard against genetic discrimination or stigmatisation based on genetic information. It is also important to guarantee either anonymisation (i.e. when the code to information does not exist at all) or at least pseudoanonymisation (i.e. when the researcher has no access to code, but the code as such exists) of samples.

Examples of existing or planned databases or registries are Eurocord (for cord blood) and a registry at the Karolinska Institute (for human embryonic stem cells). Examples of existing stem cell repositories are the UK National Blood Service (set up in 1996), NetCord and the Tianjin Cord Blood Bank in China for cord blood, and the UK National Stem Cell Bank and the Spanish National Stem Cell Bank for stem cells in general.

An important question regarding donation of cells is whether the donors should be paid. In Europe we have a gift culture, we have strong gift ethics. Donated blood is not paid for; gametes and embryos are not paid either. The question arises – how wrong would it be to pay for blood? Different cultures have different ethics. For example, in the USA large sums of money are paid for human eggs, women can pay their way through college with donation of eggs. In China, in the cord blood bank of Tianjin, they give every child free health insurance for their first 22 years (not including the first 90 days, as this is the most critical time in a baby's life). Taking into consideration that in China healthcare is not free, it can be an incentive for women to become cord blood donors. This raises another question – whether payment in money (e.g. paying cash to the donors) is different from payment in kind (like in the case of the Chinese cord blood bank). For example, the UK prohibits payment to egg donors, but egg sharing in IVF is allowed. IVF in the UK is mostly private and

expensive, and many couples can afford only one cycle and no more, whereas with egg sharing the donor can have more cycles and two women have the chance of a baby. There can also be benefit-sharing regarding the results of the research – for example in the case of DeCode Iceland, if the researchers discover new drugs, they would give the benefit of this knowledge to the population, so there is some benefit-sharing. However, the question arises of how far should it go. For example, if a young man, visiting the attic of his grandmother's house finds an old painting that he likes. The grandmother gives him the painting since she does not need it. It appears later that the painting is actually by Rubens. When the young man sells the painting and receives a lot of money, must he share this money with his grandmother?

Yet another important question is regarding the feedback to the donor – should the information be volunteered to the donor if something important is discovered. In the UK Stem Cell Bank, donors are asked whether they want feedback, and whether they want just information related to treatable diseases or also untreatable ones. If no information at all is wanted and if some information important to future reproduction is discovered, e.g. some serious genetic condition, there is a dilemma about what to do. In clinical practice, the clinical geneticists use persuasion as far as possible, if the patient does not want to tell the relatives. The question comes as to whether the same can be done in a stem cell bank.

Regarding informed consent, donors should be told that if they donate their embryos, there is a possibility for indefinite survival of the stem cell lines created from their embryos' stem cells, and that genetic data from those lines can be produced at any stage, so anonymity is not absolute. If the EU Directive requirement for traceability is to be respected, full anonymity can never be guaranteed. Therefore the donor cannot be promised that he/she will remain anonymous – only “pseudonymity” can be promised. But at least the donor's confidentiality should be guaranteed.

Another important question is whether the embryo donors should exercise any kind of future rights over stem cell lines created using their cells. Is there any reason why a donation should not be conditional? Donors could say, for example, that they donate embryos for stem cell research but they do not want them to be used for toxicity testing in companies, although they agree with their clinical uses. There is no prohibition against that sort of conditional donation in the UK. For example, in the case of using foetal tissues for research, the woman must be told precisely what is going to be done. However, it may be difficult for researchers if express informed consent must be obtained for every new research project that would take place in the distant future. Regarding the withdrawal of consent, it is and should be allowed until the cells start being used for whatever purpose.

Regarding the quality control of stem cells, different stem cell banks can meet the requirements in different ways, but it is very important that the same standards are introduced in different repositories and cell banks, for example ensuring that if the bank is closed down the cells would not be misused. Cells of poor quality should not be stored, since research on them would prove

worthless. The prospective approval of the research projects by the Research Ethics Committee also contributes to the quality control.

Regarding the ownership of cells, in the UK stem cell bank the stem cells continue to belong to whoever put them into the bank, that is, to the donor. There are problems with that, especially regarding cord blood banks. Does the blood in the cord blood banks belong to the bank or to the donor?

Another question is the payment for the cell lines: should the cells be handed to the researchers free of charge? If the researchers had to pay for them, it would become expensive if the research centre wanted to compare a number of different lines. On the other hand, charges for storage and transportation of cell lines might be necessary, but in that case they should be minimal for academic users and higher for commercial users. In Japan any human embryonic stem cell lines derived by a licensed centre must be handed free of charge to other centres in Japan licensed to do approved research projects. However, they have not yet decided what to do about handing out stem cell lines on an international basis.

Regarding patenting of stem cell lines, the EGE (European Group on Ethics in Science and New Technologies) opinion is that human embryonic stem cell lines that are modified and differentiated in a given direction can be considered for patenting. However, the European Patent Office does not grant patents on any human embryonic stem cell lines, as the whole issue is too sensitive. So there seems to be confusion between theory and practice.

In order to find solutions to all the above-mentioned problems, we should start with solutions that have already been applied in similar contexts, like blood donation. For example the issue of anonymity in blood donations – most people believe in anonymity and they do not worry about the conflict between traceability and anonymity. Most patients understand that conflict and do not worry about it. Another example is sperm donation – the donors can withdraw their consent until the donated sperm is taken to be used. The question remains whether similar solutions could be applicable to stem cell banking.