



Workshop:

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

CELL BANKING OF HUMAN STEM CELL LINES: Glyn Stacey

There is a wide variety of tissue banks. There are Public Service Culture Collections as well as pharmaceutical grade banking facilities (cGMP). The UK Stem Cell Bank encompasses all these activities while also serving as a “custodian” of key tools for research and therapeutic development. The UK Stem Cell Bank includes both somatic and embryonic stem cell lines. It operates for both research and clinical purposes: on the research level it promotes basic research and on the clinical level it serves as starting material for clinical trials. The aim of the UK Stem Cell Bank is to promote access to ethically sourced and well characterised seed stocks of human stem cell lines.

The key operational principles of the UK Stem Cell Bank are transparency, interactivity, independence and anticipation of further demands. The Stem Cell Bank must be transparent. This means that its management and procedures must be open and the audit independent. It must also be interactive with the public and the media as well as independent. Independence means that the Bank should not be involved in development of commercial products as well (as in basic research on stem cell biology). The Bank should be able to anticipate what would be the future demands and therefore it should maintain a close contact with experts in the field as well as with regulators, and be flexible in its facilities and expertise.

The Bank must also ensure that two-way traceability of the stem cell lines is guaranteed, that adequate donor testing is performed and medical histories of the donors reviewed before obtaining the biological material from donors. Adequate informed consent must also be obtained.

At the stage of data collection, the Bank must ensure the following characteristics of cell lines: purity, authenticity and stability. Purity means that the stem cell lines should be free of micro-organisms. Authenticity means that all the stored stem cells should have a correct identity and they should be free from “other” cells.

The process of stem cell banking in the UK Stem cell bank is heavily regulated and audited. All the research projects must be approved by Research Ethics Committees.

The following *questions* arise:

What to do with scientific data generated by recipients of the stem cell lines?
There must be filters applied to data handling and the data must be kept separate from the personal data.

Problematic issue:

It may be the case that at the time of donating stem cells for the Stem Cell Bank, neither the staff collecting the biological material nor the donor would know what tests will be performed on cells over time. In the near future we may see new research possibilities that were not considered when the biological material was collected for banking. Since informed consent cannot be obtained for research that is not yet known, the donor must be contacted before the newly available research is conducted on his/her donated material. This means that full anonymisation of the donated material is not possible. Full anonymisation would make it impossible to obtain new specified informed consent and would make traceability impossible.

Traceability is also problematic because it is reliant on continued contact with the donor – a situation that is not always possible to maintain, due to individuals' changing circumstances.

For imported stem cell lines the ethical requirements of the country where stem cells are banked must be applied.

Problematic issue:

A problem arises with the possible withdrawal of consent after the donation of the stem cells. If after the withdrawal of consent the stem cell line must also be withdrawn, patients may be denied of life saving therapy (if that particular stem cell line was used for therapeutic purposes). Another problem arises if the donor refuses to receive feedback and important information (also important for the donor himself/herself) is detected from his/her stem cell line. The case is even more difficult if the information discovered is not only relevant to the donor himself/herself, but could improve and save the lives of his/her relatives (e.g. in cases of genetic or infectious diseases).

In the process of obtaining informed consent the possible risks related to the data obtained from the donated biological material must be explained to the donor. The staff obtaining informed consent must be well trained to explain what will happen to the donors' cells as well as to the data obtained from donated material, if for example information on emerging diseases becomes available.

Problematic issue:

Who owns the cells in the Stem Cell Bank? Regarding the charges for “commercial” and “non-commercial” recipients, in some cases it may be difficult to differentiate between commercial and non-commercial recipients of stem cell lines. At the same time, intellectual property must be protected.

The Bank needs firm standards and good data management. There must be a robust review of feedback mechanisms as well as adequate protection against illegal supply of stem cells during international transfers.