



Workshop:

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

PANEL 1: PROCEDURES & PRACTICES IN DIFFERENT EUROPEAN COUNTRIES

Angela Barnie, Spain

The Granada (Andalusian) stem cell bank, unlike the UK bank, is a research centre, and is currently undergoing an accreditation process. Its functions are elaboration, storage conservation and management of all the types of cell lines, according to the national and international regulations that are currently in force.

To guarantee the security and confidentiality the following measures are taken:

- files with the personal data about the donor, data about the biological sample, the documents about informed consent, the processing of the sample, centres receiving the sample and centres depositing the sample are all kept separate from each other as well as separate from the code enabling traceability of the sample.
- Each, however, can be linked to the traceability code.
- There is a daily logbook, and each person has access only to their own area. Only the Bank director and the person responsible for traceability can access all the areas.
- A report is submitted to the Ethics Committee every 6 months.
- Only persons who have been given a login and password can access the database, and when leaving the computer they must either turn it off or block the screen. It is forbidden to connect to other work stations or to connect to modems.
- To ensure traceability, codes are given (e.g. 05 for the year 2005, BM for bone marrow). This coding system follows the sample throughout the whole traceability process.

It is also important to guarantee microbiological safety and minimise the possibility of contamination. All products are initially considered contagious. Bacterial, fungal and yeast monitoring is performed, as well as mycoplasma, virus, prions and other micro organism monitoring. Strict rules of biosafety are observed in the laboratory. There is also a strict review of hazardous processes.

At the time being, Spain has no biobanking laws.

Jozef Glasa, Slovakia

In Slovakia there is a long tradition of tissue grafting and banking. Novel research-based therapies were applied on cardiac patients in 2004. In 2003 an initiative started for the establishment of the commercial umbilical blood bank.

A new law from 1 January 2005 covers the retrieval, storage and transplantation of organs, tissues and cells. The tissue bank is established by state permission; it may not get any commercial gain and is subject to ministerial regulations. International collaboration in organs, tissues and cell exchange is also regulated. There will be new legislation aimed to fully implement the EC directive on Tissues and Cells.

There is also a new law in preparation – the law on biomedicine - which will address biobanks, stem cell therapies, tissue engineering, etc.

There is a very clear legal situation regarding adult somatic cells – both their retrieval and use. Their procurement, storage and use are already covered by the existing legislation, and more detailed legal provisions are in preparation. Regarding embryonic research, it is prohibited to conduct non-therapeutic research on living human fetuses and embryos. Therapeutic and reproductive cloning is also prohibited.

The possible topics for ethical debate in Slovakia are:

- financial aspects, such as commercialisation;
- data and biological material protection; ownership and patenting aspects;
- embryonic stem cell research aspects (their retrieval, import and use issues);
- embryo cloning techniques;
- the status of spare embryos and their use;
- the access to possibly expensive stem cell therapies;
- dealing with interest group pressures.

Josef Kure, Czech Republic

In the Czech Republic there are 7 stem cell lines derived from human embryos, stored at Mendel University in Brno.

The current laws in force are the Health Care Law of 1966 with many amendments and the Oviedo Convention, ratified in 2001.

There are several laws in preparation: a new health care law, law on research, law on human embryonic stem cell research (the latter is legislatively most advanced). The draft law on human embryonic stem cell research states that the source of these cells will be surplus embryos and no creation of embryos for research purposes is foreseen. The law also requires informed consent of the donor, prohibits commercialisation of human embryos as well as their implantation after research has been conducted on them. Regarding import and export, it is only stem cell lines that are allowed to be

imported and exported, and can only be obtained in accordance to the law of the country from which they are imported. The draft law proposes that the institution where stem cell lines are stored will be the owner, based on informed consent of the donors.

Opinions about the establishment of a stem cell bank in the Czech Republic differ. Some say that such a bank is needed, others oppose. The draft law proposes to establish a stem cell lines database, administrated by governmental authority. A clear origin of the embryo is required, based on the informed consent of the woman, and also of her husband, if she is married. The draft law also requires ensuring traceability as well as confidentiality, provided that the donor is informed about the requirement for traceability as well. All registers would have two different areas. The public one would have open access, while the other area with confidential information would have restricted access. Any movement or transfer of stem cell lines must be registered and documented (e.g. if they are provided to another research institution). The draft law also requires transparency and data protection – by granting an open access to the database and having no requirement to declare the purposes for access, but at the same time observing the personal data protection law. The law foresees that the state would have a total control. If an institute declined access to enable this control, they could receive high fines or have their license suspended. Only research on registered stem cell lines would be allowed, and registration would have to be done within 10 days of the establishment of the stem cell line.

Stem cell researchers in the Czech Republic were surveyed. According to this survey, leading researchers suggest adopting the UK approach (even to the extent of creating embryos for research purposes).

Morality is perceived to be a private issue in the Czech Republic. Public morality is often perceived as restriction. The state has a secular approach (70% of the population are atheists or agnostics and 30% are believers). The influence of Christian churches is marginal and there is no tradition of a religious legal approach.

On the international scale, the different regulatory and legal restrictions in Europe could be viewed as a disadvantage – stem cell research is more advanced in some European countries, resulting in competitiveness. A European Stem Cell Forum could be established, to deal with the scientific, ethical and legal issues of stem cell research. Another suggestion would be to create joint repositories (with the same safety requirements, the same standards) as well as to allow open access to an embryonic stem cell database (since it is a societal heritage), while ensuring the protection of intellectual property and confidentiality. It might also be beneficial to create a similar structure to Euroatom, e.g. Eurostem.

Joze Trontelj, Slovenia

In Slovenia there is a law on medically assisted reproduction, which bans cloning, both for reproduction and research purposes. It also bans the creation of embryos for research. Research is allowed on stored embryos that

are no longer part of a parental project or are destined for destruction after expiry of storage period, and informed consent of the couple is required.

In Slovenia there are 21 cryopreserved embryos potentially available for research. There is currently no research on embryonic stem cells and there are no plans for an embryonic stem cell bank. There are no obstacles, however, to the creation of stem cell banks, and no obstacles to ethically acceptable and scientifically valid stem cell research.

A bank of stem cells derived from placenta/umbilical cord is being created and a bank of stem cells derived from bone marrow is in operation. There is a project to use autologous chondrocytes for the treatment of osteoarthritis, as well as the use of autologous osteocytes for alveolar bone grafts in dental surgery and autologous keratinocytes for skin grafts in the treatment of burns.

Henk van der Zanden, STEMNET

Stemnet partners are Lithuania, Poland, Czech Republic, Slovakia, Hungary, Slovenia and the Netherlands. In these countries there are well-established registry structures and procedures according to the standards of the WMDA (World Marrow Donor Association).

General threats to the cell and tissue banks are fire, flood, robbery, molest, stupidity (stupid mistakes) and now we can add that the information society is also a threat.

There are also threats to the information system, such as loss of information (so there is always a need to have the backup of the information), erroneous information (to prevent this only authorised access should be allowed and good laboratory practice rules should be strictly obeyed), manual input of information (which could be changed by electronic data interchange) and system manager interactions (therefore logging is necessary). The threat to the privacy could be the possible access to data by the cleaning or security servicemen.

The WMDA standards are that the donor and patient identity must always remain confidential. During the search process the initial donation must be anonymous. The donors or their families may become poor; they may start begging the patient for financial support. Or if the patient gets ill, there may be a pressure on the donor or his/her family for a second stem cell donation. The initial donation must always remain anonymous. The Registry must have a written policy listing the conditions under which donors and recipients might be informed of each other's identity.

There are a number of ethical questions related to the requirement for donor and patient confidentiality. For example, can registry staff be a donor? And what to do if a registry staff member becomes a patient? Being an employee of the registry, you can find out who is the donor. Can the patient and donor be in the same hospital or in the same department? The adequate education of the staff can help to deal with those problems, and it would be possible to have donors and patients in the same department, without disclosing their identity. It is important to look at WMDA standards when creating new legislations.

Questions:

Is it a problem that the Oviedo Convention was negotiated before the derivation of human embryonic stem cells became possible? The Convention prohibits producing embryos for research purposes. However, in any of those countries that have ratified the Oviedo Convention it is legal to prescribe the oral contraceptive pill, which prevents an embryo from implanting, which happens on day 6 after the fertilisation of the egg. So what is the difference between human embryonic stem cell research using embryos created for research purposes, and allowing oral contraception? In stem cell research the embryos are created to combat human diseases, so using them for this purposes grants the greater respect that destroying them by using oral contraception. If the countries allowing oral contraception do not allow creation of embryos for research purposes on the grounds of protecting their dignity, they are being inconsistent, since the moral basis is the same. The point of consistency is a very strong one in ethics.

Answers:

If there are strong review committees for embryonic stem cell research, it is then very different from oral contraception. This point confuses two different settings: research and the so-called therapy. We should distinguish between research and therapy.