



Workshop:

Ethical aspects of stem cell repositories and stem cell databases
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PANEL 2: INTERPRETATION AND IMPLEMENTATION OF RELEVANT LAWS AND DIRECTIVES

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There are 25 member states in the EU. The legal basis of the EU is the EC/EU Treaties. The Treaty of Nice binds all the member states. However, it is difficult to agree on international ethical principles, and member state can have more strict regulations than the ones in the EU treaties.

The objective of the Art. 152 of the EU Directive 2004/23EC (human tissues and cells directive of 31 March 2004) is public health protection and defining its minimum standards. Art. 152 states that member states must adopt “measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives” and that these measures should not prevent “any member states from maintaining or introducing more stringent protective measures”.

Art. 152 allows establishing binding standards to all issues related to the quality and safety of organs, blood and substances of human origin. It does not allow the establishment of binding requirements on non-safety and quality issues (e.g. ethical issues). No harmonisation of this provision is ensured under Art. 152, and it does not affect member states’ responsibilities in health care or the organisation of donation of organs and blood. Directive 2004/23EC is the parent directive with main requirements. The technical requirements will be in other documents. They will establish a structure in charge of supervision of tissue procurement, the notification system for serious adverse reactions, the quality system, including training, as well as the coding system and the requirements for direct distribution to recipients.

Directive 2004/23EC established requirements for the inspection and accreditation of tissue establishments, quality and safety requirements for tissues and cells, the mechanisms of control of import and export, the requirements for traceability as well as ethical aspects. It established the requirements for accreditation and inspection structures, the supervision of tissue procurement, accreditation, designation, authorisation or licensing of tissue and cell establishments, as well as of tissue and cell preparation processes. The Directive also requires establishing a register of accredited tissue establishments, inspection and control measures and guidelines for

inspections as well as notification system of serious adverse events/reactions and a system for import/export.

The safety and quality requirements addressed in the Directive are the ones to establish the selection criteria for the donor and the recipient, the laboratory test required for donor, the cell and tissue procurement procedures and reception at the tissue bank, tissue and cell processing, preservation and distribution, the quality system and the coding system as well as requirements for the direct distribution to the recipient of specific tissues and cells.

The ethical aspects reflected in the Directive are as follows:

- donation should be voluntary and unpaid; the procurement of tissues and cells may be performed only on a non-profit basis,
- the consent and provision of information is mandatory,
- the data protection and confidentiality of donors and recipients must be guaranteed.

The third Commission Directive for import and export will appear next year. The Tissue Directive is like a net directive that will cover all the other ones. Any specific Directive in the future will cover more details, but within the borders of the Tissue Directive.

The Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use is another important directive. It was amended by the Commission Directive 2003/63/EC of 25 June 2003.

The difficult question is to identify the boundary between tissue products and health impacts. There is a need for harmonization of laws and guidelines in the European community.

Elisabeth Rynning

Stem cell repositories and data banks – the legal aspects

On the EU level, for example, the following documents relate to the issue of cell banking to a lesser or greater degree: the Directive 95/46EC on the protection of personal data, the Directive 98/44EC on the legal protection of biotechnological inventions and the Directive 2004/23/EC on setting standards of quality and safety for human tissues and cells. On the Council of Europe level, the following documents relate to this issue: the European convention on the protection of human rights and fundamental freedoms (1950) and the Convention on Human Rights and Biomedicine (1997) with additional protocols.

The difficult question is what approach to choose in the legal area when we discuss stem cell banking. There is also a further challenge for regulation, since many terms are not yet clearly defined.

One question to answer is whether cells are a form of information carrier or something quite different. How far should they be regarded as “parts of the human body” or as information? And how should we perceive stem cells and stem cell lines? To what extent and how should we interpret the articles of the

Convention on Human Rights and Biomedicine on non-commercialisation? And to what extent does the Data Protection Directive apply to human cells as information carriers? The Directive refers to any information. How will the information in human cells relate to data protection laws? Where does the applicability of one Directive end and the other begin? Should there be double standards for data protection in stem cell repositories regarding the issues of consent and its withdrawal, access to information and confidentiality, international transfer and other issues? To what extent do ordinary data protection principles apply to human cell material? Where is there special legislation that applies to human biological material and how does it relate to data protection laws?

Another question is when donated human cells become products, if they are products. At which point should different rules start applying? When cells are processed they are turned into something else - are they then still treated as parts of human body? Does the donor anonymity matter in this case; does it have to be protected? At which point does commercialisation become unproblematic? Depending on the purpose of the legislation, different laws may provide different criteria on when the cell stops being a part of a human body and is turned into a product, and to what extent donor's autonomy and privacy should be protected, to what extent property rights should be protected and what should be the product safety requirements. Patent laws, for example, push the limits to perceiving the processed cells as products.

Yet another important question is whether we can have fairly free access to stem cells. We must only allow justified access to research persons. We must address issues of property rights and product safety, take all into account and answer the question on where are the limits of unjustified commercialisation.

There is a tension between the requirements for anonymity and traceability. A sample cannot be at the same time traceable and anonymous, or can it? The answer depends on how these concepts are defined and what we mean when we talk about identifiability and anonymity. So far there is no European consensus on the definitions and terminology. What should be the criteria for traceability/unidentifiability of data – absolute or reasonable? Should coded data and cells be considered as traceable and is “anonymous” the same as “unidentifiable”? The Data Directive prescribes that “account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person”. In some countries there is a strict standard whereas others focus more on the word “reasonable”. In some countries, if the person using the data has no key, the data is regarded as non-identifiable. In countries with the more strict standard, the data may be regarded as still identifiable, if the key exists. For example, according to the European Medicines Agency – anonymous means that it cannot be linked or traced back to the person. But can cells be truly untraceable, since they contain the DNA? We must find the definitions that are reasonable in these contexts.

There are different ways to address the same issue: either make additional provisions in the already existing laws, or pass a separate act. For example, Iceland has an Act on Biobanks since 1 January 2001; Finland has added relevant provisions to their Transplantation Act, (the Act on Use of Human

Organs and Tissues for Medical Purposes, 1 September 2001; Sweden and Norway have Biobank Laws (Act on Biobanks in Health Care, 1 January 2003 in Sweden and Act on Biobanks, 1 July 2003 in Norway); Denmark has added new provisions in their Act on Ethics Review, 1 June 2003 as well as in Patients Rights Act September 2004.

In Denmark tissue samples in a biobank are also covered by the general Data Protection Act, whereas in Sweden such samples are not covered by the Data Protection Act. In Sweden there are different rules that apply to repositories and databases linked to them. There is a Data Protection Law for data and a Biobank Law for samples – the Biobank Act does not cover all repositories. The key concepts remain unclear - when the sample is traceable and when not, and at which point it becomes a product. In Denmark there is no problem to send the samples to other EU states, but there are strict regulations about that in Norway and Sweden. In the Swedish Biobank Law there is also a special legislation on foetal tissues and embryos. It has recently been decided that creation of embryos for research purposes as well as SCNT (somatic cell nuclear transfer) is allowed.

Human cells are both information carriers and live raw material of extraordinary potential. The challenge is the varying background, focus and legal competency in the public international law, the EU law and national legislation. If we want to further free movement and collaboration, we must have similar methods and level of judicial protection necessary for free movement and cross-border co-operation. We must harmonize or at least coordinate the laws both between the states and within them. For example, the regulations on data and on samples. This requires not only agreement on principles, but key concepts involved must be agreed upon, defined and clarified.

Now the challenge of agreement leads us to use vague concepts, when we really need more clear criteria. For example, if we use somatic cell nuclear transfer to create an embryo, it may be argued that it is not an embryo since implantation is prohibited. But on the other hand, the organism created still develops like a human embryo does. Another example is the difficulty to find a dividing line between data and sample. We must also find some way of defining the degree of manipulation or merging with something else that is to be required for human biological material to become a product and no longer viewed as a part of human body.