Feb. 15, 2012

MINUTES

Meeting with representatives of National Health Authorities and representatives from the Scandiatransplant board and office and lawyers from Region Central Denmark

Purpose of the meeting:
To clarify how the individual national health authority will manage registration of Nordic and national data on organ donation and transplantation as stated in the directive 2010/53/EU.

- How will each national health authority ensure legal aspects of the duty of the inspection of the obligations stated in the directive?

Time: December 12, 2011 at 11:00-14:00

Place: Meeting room at Socialstyrelsen, Rålambsvägen 3, Stockholm

1. **Welcome and introductory remarks. Krister Höckerstedt:**
   These issues have been discussed at the Nordic Transplant Committee meeting between representatives of Health Authorities and the Scandiatransplant board in Reykjavik, September 20, 2011. This extra meeting had the following 2 specific purposes:
   1. Is there a will and a possibility in the Nordic countries to have a similar list of data to be included in the respective national registries required by the EU 53 Directive?
   2. Would it be feasible to continue the system of collecting and sending national and center data respectively to Scandiatransplant which transforms the data into a form requested by EU?

2. **Housekeeping information given by Charlotte Möller.**

3. **Election of writer of the minutes**
   Charlotte Möller eventually with supplements.

4. **Adoption of the agenda/additional issues:**
   OK.

5. **Short introduction of the participants:**
   Short presentation by each of the 18 participants. The partipants from Norway could due to the weather situation not come from Oslo airport but participated by phone. From Iceland 1 participant joined the meeting over the phone.

6. **Presentation of the association Scandiatransplant:** An association situated in Denmark and operating according to Danish jurisdiction and a certificate of registry of data under the auspices of Region Central Denmark (one of five health regions in Denmark). Scandiatransplant is owned by the Transplant Hospitals in the Nordic countries.
   6a. Niels Grunnet: Short overview
   6b. Frank Pedersen: Sctp datasystem versus 2010/53/EU.
   http://www.scandiatransplant.org/sctpvseu.html
   6c. Annette Sand: Legal aspects

The association Scandiatransplant was presented by
Krister Höckerstedt: Rules for exchange within the cooperation
Niels Grunnet: Short overview of the system (10 dias).
Frank Pedersen showing online aspects of the Scandiatransplant datasystem versus directive 2010/53 EU.
Annette Sand on the legal aspects: Scandiatransplant is a private organisation with bylaws last revised 2006. Article 3 of the bylaws was read aloud (enclosed).

Security of processing data.

The EU Directive 95/46EC on the protection of individuals with regard to the processing of personal data and the free movement of such data, has been carried out in "The Act on Processing of Personal Data" in Denmark.
The Danish Data Protection Agency is responsible for the supervision of all processing operations covered by the law.
The Scandiatransplant office in Aarhus is running the Scandiatransplant database and the database is operated according to Danish jurisdiction of laws with Central Denmark Region as a controller and with Scandiatransplant as a processor.
According to the existing laws, the controller and the processor are obliged to make all the appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, abuse and against all other forms of processing.
According to "The Act on Processing of Personal Data" shall all processing of data of a confidential nature, carried out on behalf of the public administration, be notified to the Data Protection Agency.
The data processing in the Scandiatransplant data base, has been notified under the auspices of Central Denmark Region.
You can see the notification to this in the material sent out to you.
"Anmeldelse af behandlinger der foretages for den offentlige forvaltning" – jr. nr. 2007-58-0008 – Patientbehandling i regionalt regi. ("Notification of processing carried out for at public administration").
With the EU Directive 95/46EC and the national laws carried out in the EU and also the EØS contries, you have established a system of rules that basicly are the same in all the EU contries. According to that, all processing of personal Data in the EU and the EØS contries are considered safe.

Rules for preserving confidential informations

In Denmark we have at set of rules to preserve the confidentiality of your medical condition and personal relations.
The Health Legislation contains rules for professional secrecy, disclosure and handling of personal informations. There are also rules for transplantation of organs and rules for reporting unintended incidents.
According to the rules, it is possible to handle over personal informations about a patient, if it is necessary for the treatment of the patient.
If you want to handle over informations for other purposes than treatment, you have to obtain an informed consent from the patient.
The informed consent shall be in writing and noted in the journal in each department. Each department shall inform the patient about the purpose for the registration and to whome the informations will be given to.
The patient can at any time withdraw the consent.

According to data handled to the Scandiatransplant database, it is necessary to make sure that this consent is obtained and noted in the journal.
Each department are responsible for obtaining the consent and for its documentation.

The future role for Scandiatransplant from a legal point of view

The first bill in Denmark to implement the Directiv 2010/53/EU of 7. july 2010, has been started off with a hearing in Denmark in October/November 2011.
The bill makes an opportunity to let an organization take care of different tasks on behalf of the Danish Health Department.
This organization could be Scandiatransplant.
It is not clear if the other 4 countries will make this opportunity too, but if that is the case there will be some considerations for the association.
The members of Scandiatransplant shall decide if the organization wants to take care of these duties on behalf the authorities such as:

- control of exchange of human organs between contries
- keeping data in order to trace organs
- (reporting accidents and severe adverse effects (SAE))
- controlling keeping the rules
- running the database with other (extended) purposes
- making annual reports to Nordic national authorities, EU, transplant centers and others.

If the purpose for Scandiatransplant is going to be changed or extended, it can be necessary to change the by-laws and the members fee.
It will also be recommended that an agreement with the authorities in each country about the details and payment for these assignments is made.
From at practical point of view, it will also be necessary that the 5 countries represented in Scandiatransplant, has equal systems and rules.

The role of Region Central Denmark

As it is now, the Region is controller of the Scandiatransplant database and is providing an office and some other facilities at Aarhus University Hospital, Skejby, Denmark.
These facilities may not be enough in the future for Scandiatransplant if the organization needs more staff and at larger office and so on.
A formal agreement between Scandiatransplant and Central Denmark Region about the cooperation should be worked out also about the costs.
These are some of the considerations to have in mind.

7. **Directive 2010/53/EU. Implementation of mandatory data in national registries by August 27, 2012**
   - Will the three EU countries (Finland, Sweden and Denmark) and the two EØS countries (Norway and Iceland) create their own registry to fulfill the Directive?

From Norway, Denmark and Iceland it is indicated that it looks as if the purpose is to use the Scandiatransplant register systems. Sweden is in the beginning of making a new law as a consequence of the Directive; in a proposal for the law there is suggested a national register to give the public transparency of the activities. The details on such a registry and the licence by the authority is at present unknown, but when the law makers have drawn the line then Socialstyrelsen can make rules for management rules. At present the solicitors in the Swedish Health authority think that it is difficult to regulate the role of Scandiatransplant technically and legally. Therefore cooperation can be dependent on which legal solutions the authorities can agree on.

Finland has already a national registry at Helsinki University Hospital. This can be supplemented to meet the demands of the directive. Probably Finland would use this national registry also in the future. From this registry, data is given further on to the Scandiatransplant data register, but at the present time it is discussed how the national registry in Helsinki will be incorporated in the law system in Finland.
Denmark is in a process of creating a new transplantation law. The purpose is during agreements to use the registers of Scandiatransplant and delegate specific issues in this context.
Iceland has not yet decided how to implement the directive's issues.

- Reporting of severe adverse events shall be established in each country separate from the Scandiatransplant system (for example in Denmark we have what is called a system for registration of "utilsigtede hændelser" = unexpected events).

8. **Register for organ transplantation using living organ donors:**
   Scandiatransplant has a register facility to offer. If this is accepted there shall be defined a minimum dataset being mandatory to fill into the Scandiatransplant datasystem within a certain time limit.

9. **Establishment of agreements of cooperation between each national health authority representing all transplant centers within that country and the Scandiatransplant organisation/Scandiatransplant office under Region Central Denmark:**
   A number of agreements have to be written and accepted before it is clear which role the Scandiatransplant organisation shall have in relation to implementation of this EU Directive. The Danish national board of health was asked to write a proposal for an agreement between one national health organisation and Scandiatransplant organisation for delivery of data. Danmark was pointed at because the Scandiatransplant association is situated in Denmark and therefore under Danish law systems.

10. **Bylaws of the Scandiatransplant association**: If agreements will necessitate changes in the bylaws of the Scandiatransplant organisation the final text for proposal of changes of the bylaws = agreements = articles of association for Scandiatransplant has to be finished in the beginning of April 2012 to get through the process of decisions at the Council of Representatives' regular annual meeting, scheduled to May 9, 2012.

11. **Economical aspects of agreements between each national health authority and the Scandiatransplant organisation:**
    Each agreement will probably demand a fee to the Scandiatransplant organisation for defined data delivery.

12. **Time schedule for feed back and contact persons for legal binding statements under the degree of cooperation between each country and the administrators of the Scandiatransplant datasystem:**
    A follow-up meeting is decided to be April 16, 2012 at National Health authority Copenhagen from 13:00 pm.

13. **Any other business**: **Exchange of knowledge between health authorities and inspiration from papers? (e.g. United Kingdom):**
    From homepages some information was reported.

14. **Conclusions:**
    Probably Denmark, Norway and Iceland will use registration of national data via a Scandiatransplant system in one way or another. However the precise way of handling this could not be defined and will be discussed at the next meeting.

15. **End of meeting.**