

Nordisk Transplantationskomité

/nordtxkom/ Minutes meeting No. 11 sept 26, 2006 Helsinki

MINUTES OF MEETING

Meeting No: 11
Time: Sept. 26, 2006
Place: Ministry of Social Affairs and Health,
Meritullinkatu 8, Helsinki, Finland

Meeting participants:

National Health Authority representatives:

(HG) Håkan Gäbel, The National Board of Health and Welfare, Stockholm
(JS) Jorunn Svendsen, Social- and Health Authority, Oslo
(BUK) Bjørn Ursin Knudsen, Health Authority, Copenhagen
(MK) Mervi Kattelus, Ministry of Social Affairs and Health, Health Department, Finland
(ÅW) Åsa Welin, The national council for organ and tissue donation, Stockholm

Apologies received from:

(SM) Sveinn Magnússon, Ministry of Health and Social Security, Reykjavik

The board of Scandiatransplant:

(AJ) Arnt Jakobsen, Oslo
(LK) Lauri Kyllönen, Helsinki
(MO) Michael Olausson, Gothenburg
(PF) Per Pfeffer, Oslo
(SSS) Søren Schwartz Sørensen, Copenhagen
(MB) Magnús Bødvarsson, Reykjavik

Medical director, Scandiatransplant:

(NGR) Niels Grunnet, Aarhus

The meeting followed the previously submitted agenda with supplements.

1. Welcome

Welcome by the host Mervi Kattelus and by the chairman of the board of Scandiatransplant Arnt Jakobsen. New participant since the last meeting is Åsa Welin, operative manager, The National Board of Health and Welfare, Stockholm, chairman of the National council for organ and tissue donation, and member of the board representing Sweden: Michael Olausson who in addition is president of the Swedish Transplantation Society.

Each participant presented himself/herself shortly.

2. Election of chairman of the meeting and writer of the minutes

AJ was elected as chairman of the meeting, NGR was elected as writer of the minutes.

3. Approval of minutes from meeting No. 10

Approved.

4. Additional issues for the agenda from the participants

Consultation Document: Organ Donation and Transplantation Policy Options at EU Level dated 27 June 2006. Copies were distributed to those who had not got it (see below).

Implementation of the EU directives on tissues and cells (2004/23/EF). The tissue directive shall be implemented in the member states by April 7th, 2007. From Denmark it was told that the tissue law was adopted April 1st, 2006 and ministerial orders of July 2006 from the Ministry of Health were now in the process to be realized with applications from tissue centers before October 1st, 2006 followed by evaluation and inspection with licence to approved centers before the end of March 2007. The administrative process was still ongoing in Finland and Sweden and expected to be settled in the near future. In the directive article 2 issue 2c it is stated that organs or parts of organs being intended to be used with the same purpose as the whole organ in the human body is not covered by the tissue directive. This is also clearly stated in the Danish version of the ministerial order (nr. 753 af 3. juli 2006 Ministry of the Interior and Health, Denmark). Then there was a discussion because it was the opinion by the Swedish and Finnish representatives that pancreatic islet cells probably was covered by the EU directive for tissues and cells. A copy of the ministerial order was distributed to participants, and in addition an indication of contact persons at Danish Medicines Agency, Copenhagen to clear out if we could have the same interpretation of the directive in all the EU member states and EEA countries. From members of the board of Scandiatransplant it was stated that pancreatic cells is part of an organ because pancreatic islets is not only beta cells, but also accessory cells in the islets, and therefore it is mini organs, very different from the other types of cells covered obviously by the directive for tissues and cells. The question was raised how is it interpreted in Europe? Scandiatransplant had earlier defined pancreatic islets as part of an organ and therefore made it equal to an organ transplantation. During the meeting it was stated that Michael Olausson will take contact to the central person in pancreatic islet transplantation (Olle Korsgren, Uppsala). Several of the representatives of health authorities stated that they do not want to disturb the possibility of transplanting pancreatic islet cells and to have research programmes as that in Uppsala, Sweden. There was also an agreement that it is necessary to have the same definitions and interpretations in all the Nordic countries. (After the meeting, NGR took contact to Danish Medicines Agency, Michael A. Cox who would explore the area by looking at the definitions at a tissue agency in the UK plus discussing it with some central persons at EU being responsible for the EU directive and who could elaborate what was the intention of the text). Certainly members of the Nordic Transplant Committee will follow these issues.

Consultation Document:

It is a document open for consultation towards the European Commission: Somebody wants to make EU directives on organ transplantation also. The document is well-written and some of the options can be accepted by the Scandiatransplant board, but they also have some comments which will be set up in a document sent to the address for responses. It was said that there was no official reaction from the ministry in Finland, but that there had been comments from Kaija Salmela and Krister Höckerstedt. From Sweden 6 individual expert opinions had been sent. The ministry as such in Sweden had not replied, as is the case for the ministry in Denmark. The board of Scandiatransplant has several worries about the present open document:

1. Too little is said about transplantation using living donors

The way of allocation in the Nordic countries is apart from the way in Eurotransplant and in other systems using a more mathematical system by giving points for several parameters which can be summarized in a more "justice" way of allocation. This is in contrast to the way of doing it in Scandinavia where the principle is more utilitarianistic meaning that all aspects to have best use of the individual organ is taken into consideration.

The board of Scandiatransplant will response on the consultation document via its chairman Arnt Jakobsen (The response has been worked out and sent to EU on Oct. 13, 2006).

5. Organ transplantation activity in 2005 in the five Nordic countries

Copies were given of relevant figures for 2005 supplemented with a survey of the figures for the last 10 years. The data were discussed and supplemented with the following information: In Scandinavia, the basic principle for allocation is careful medical selection to have the best use of organs not based on a mathematical point system (justice principle). An organ in an aeroplane is not the best place for an organ therefore there has become very reasonable level of organ exchange within the countries/transplant centers of Scandiatransplant. Another comment is that according to the European way of reporting organ transplantation and patients on waitinglists both patients being active or inactive on a kidney waiting list are now taken all together. This means that dead on waiting list could look as if it has raised but it is simply a consequence of another way of reporting the data. We have earlier used the word necro or cadaveric for donor of organs. This word is now replaced by using the word: Deceased.

From health authority participants it was stated that it is important to have data concerning organ transplantation. On the homepage of Scandiatransplant you can only see aggregated data covering the whole Scandiatransplant or each country. In case one wants to know more detailed figures it is a possibility to get these from transplant coordinators in each country, or to ask the Scandiatransplant office if it is some figures that can be delivered.

**6. Council of Europe, Alliance-O activities and EURO CET
(Supranational organisation versus national organisation)**

Eurocet (European Registry for Organs, Cells and Tissues): This is an IT EU project with representatives mainly from the transplant organisations in Estonia, France, Italy, Poland, The Czech Republic, Slovenia, UK, Spain and Hungary plus Eurotransplant.

Scandiatransplant has had a role as observer and has no plan to be regular participant.

Alliance-O is another co-work in Europe chaired by the French organisation: Agence de la Biomedecine. So far several workpackages were formed, one on organisation and coordination, another one on expanding the donor pool, a third on allocation: Comparison of allocation rules and preparation of own unique rules, a fourth on safety and quality, a fifth with coordination of evaluation methods of transplantation performance, a sixth on fundamental research activities related to organ transplantation, and a seventh on comparison of ethical and legal aspects. The chairman Arnt Jakobsen has participated in an External Advisory Board in the context of Alliance-O.

Council of Europe has had its SP-CTO being the committee of experts on organisational aspects of cooperation in organ transplantation within the council of Europe. The council of Europe wants to put less money in activities like the SP-CTO. Until now this committee works within an intergovernmental programme of 46 countries. The activities of the committee must be transferred to an existing partial agreement. The choice has to be made between two partial agreements: Public health and pharmacopoeia. There had been taken a painful decision that the expert group should be under pharmacopoeia.

Some other countries like Denmark will not accept the partial agreement and are therefore working towards an engagement with WHO. Several of the participants expressed that it is

a pity that the group SP-CTO will discontinue with its previous work. The future will bring what will come instead. The board of Scandiatransplant will ask the health authorities to be very observant and influencing the developments so that the regulatory affairs will be influenced to the highest possible level of input from medical professionals within organ transplantation. This is of great importance to keep on the level of organ transplantation. From other meetings one can get the impression that somebody has the impression that common waiting lists in Europe or a great frequency of organ exchange will increase the number of organs or the number of transplantations. However, this is not the case as judged by those having worked professionally with organ transplantation for years.

7. Guidelines for deceased organ donor transplantation of non-Nordic nationals within Scandiatransplant

See minutes from year 2005 issue 6. The board of Scandiatransplant has made some guidelines in May 1995 and reapproved them in 2005. There was a question if the health authorities of the five Nordic countries could have a look on these guidelines and see if these are in harmony with laws in the individual Nordic countries? The issue is still discussed in the European context because you have an increasing number of individuals moving over borders and this gives some different cases that have to be handled with respect to the conventions in EU and the laws in the individual member state or EEA (European Economic Agreement) country. Then there was a discussion on transplant tourism and it was agreed upon that rules should be common in all the Nordic countries concerning tourists "coming to a Nordic country to be treated". As far as we can judge the rules are rather equivalent for the time being.

8. European Organ Exchange Organisations (OEO)

Representatives from the individual organ exchange organisations in Europe meet once a year within this context. A common contract of organ exchange between organisations has been worked out. Each individual patient can only stand on a waiting list in one organisation at a time. From Poland there has been an unofficial request to the transplant center in Gothenburg on some sort of organ exchange. This case was referred via the official routes and the problem has been taken care of by the authorities in Poland. Another issue is transportation of organs in Switzerland. They have had difficulties with airplanes not allowing these boxes with organs to be transported with their airplanes. Living organ donors are now registered for a long life follow up. Such registers have been set up in several organ exchange organisations, although some countries have seen some difficulties because of data protection aspects. In Scandiatransplant the register is now up and running. In Holland they have had experience with crossover transplantations, that is fx. a living kidney donor that cannot give to his own family member due to for example ABO incompatibility and the kidney is then transplanted to a recipient in another pair whose donor can give to the recipient of the first pair. There have been a few examples of experiences of this in Sweden.

One issue that Scandiatransplant will raise in the next meeting will be on the phenomenon of redelivery of an organ. It is well-established within Scandiatransplant that if one center has to exchange a kidney to another center due to HLA matching etc., the recipient center has to redeliver a kidney within 6 months to the donor center. This keeps the exchange in balance and keeps the motivation at a very high level. However, in the context of exchange between two organ exchange organisations this has so far not been realizable to set up such a redelivery system.

9. Scandiatransplant's datasystem situation; status regarding the renewal and financial situation.

The present data system has been developed in the beginning of 1990'ies and therefore there is a need for some technical updating. The project has been started and is now in phase 1 of this. Scandiatransplant has collected some money during the recent years and has therefore had some funding for this change of the data system. However, one can expect more costs before the system is fully renovated.

10. Scandiatransplant's application for financial support from the Council of Nordic Ministers

Therefore Scandiatransplant has sent an application to the Nordic Council of Ministers of DKK 3 millions. The application shall be looked at in October 2006. It is very valuable to get fx. ½ million each year over 3 years which will be a great help in this renovation process. As you all know the Scandiatransplant organisation was in the beginning supported by the Nordic Council of Ministers. Therefore the board of Scandiatransplant hope that it will be possible to be economically supported by this Nordic activity, because Scandiatransplant has been one of the great examples of cooperation between the five Nordic countries.

11. Pancreatic islet transplantations within Scandiatransplant (regarded as organ transplantation and not tissue).

See above. As indicated Scandiatransplant has regarded pancreatic islet transplantations as an organ transplantation and not a transplantation of a tissue. However, this is under debate for the time being in the context of the EU directive on tissues and cells. The problem has to be solved hopefully in a way so that it will not disturb the very brilliant work within research and development of this area, with the leading center Uppsala and with activity in Oslo and somewhere else. It is of great importance for organ transplantation and patient treatment with organs or parts of organs like islets of pancreas that the area will not be regulated in a way that will destroy the possibility of development.

12. Rules for allocation of organs for transplantation within Scandiatransplant

Within Scandiatransplant a set of rules have been worked out for each organ concerning rather simple rules for allocation bringing in front the optimal use of the available organs for transplantation instead of using a point system which will lead to a greater number of organs to be moved from a donation center to a recipient center without any benefit for the patients. On several occasions in the world the issue of allocation of organs for transplantation is discussed and evaluated. It is the hope of the board of Scandiatransplant that we can continue with the present rules for kidneys, hearts, lungs, livers for the benefit of the waiting patients.

13. Other issues

None.

14. Next meeting 2007

Next meeting is going to be September 18, 2007 in Oslo, Norway probably from 12.00-16.00.

15. Any other business

Thanks to the health authority of Finland for hosting the meeting, for a very valuable discussion and exchange of opinions, and especially that we had focus on the two very important issues. The first: Implementation of the EU directive on tissues and cells. And second: The open consultation document from EU on the first steps towards a regulation of the area of organ transplantation.

Writer of the minutes: Niels Grunnet