

Sept. 28, 2015

## MINUTES OF MEETING

**Meeting No: 20<sup>th</sup> meeting in the Nordic Transplant Committee**

**Time:** Tuesday, Sept. 22, 2015 at 12:00-16:00

**Venue:** Danish Health and Medicines Authority, Copenhagen.

### **Participants:**

Competent Authorities:

Norway: **Jorunn Svendsen, Marit Kildal**, Norwegian Directorate for Health

Finland: **Jaakko Yrjö-Koskinen**, Ministry of Social Affairs and Health.

**Pirkko Puranen**, Finnish Medicines Agency Fimea

Sweden: **Carin Franzén, Josefina Eggertsson Meyer**,

The National Board of Health and Welfare.

**Mona Hansson**, Inspektionen för vård och omsorg (IVO)

Denmark: **Bjørn Ursin Knudsen, Anne Cathrine Bollerup, Kristina Helm**, Danish Health and Medicines Authority,

Iceland: Nobody

Scandiatransplant:

(KH) Krister Höckerstedt, Helsinki

(HI) Helena Isoniemi, Helsinki

(LW) Lars Wennberg, Stockholm

(PDL) Pål-Dag Line, Oslo

(MA) Margret Andresdottir, Reykjavik

(FG) Finn Gustafsson, Copenhagen

(KAJ) Kaj Anker Jørgensen, Aarhus, Medical Director.

Sim Suutre, State Agency of Medicines, Estonia, participated in the beginning of the meeting as an observer.

### **1. Welcome:**

Anne Cathrine Bollerup welcomed everybody to the meeting and then gave the word to Krister.

### **2. Election of chairman of the meeting and writer of the minutes:**

Krister Höckerstedt was elected chairman of the meeting, and Kaj Anker Jørgensen writer of minutes.

**3. Approval of minutes from meeting No. 19, 2014:**

Minutes approved with no comments.

**4. Additional issues for the agenda from the participants:**

Krister Höckerstedt asked for “organ donations and transplantations of refugees” to be put on the agenda under any other business. This was accepted.

**5. “Legal memorandum on the structure forming the basis of the services which Scandiatransplant and Region Central Denmark offer hospitals in the Nordic countries”. (Kaj Anker Jørgensen):**

KAJ gave a short overview of the status of data legality at the time being and pointed out grey zones and unknown legality. He felt there was a need for a document describing a model, which would be legal in all countries. He then demonstrated how the database is built up and who can access it in different situations. The legal memorandum had been sent out before the meeting and there were many comments especially from Finland and Sweden. It seems clear that lawyers from different countries have to be involved, before we can agree on a model. A proposed model is that each member hospital is the owner and the responsible, liable party for the data. The responsibility for correct allocation is the doctors performing donor operations, but Scandiatransplant is the tool to ensure that the organs are allocated correctly. After some discussion it was agreed that there should be made a working group with participants from all countries. This group does not have to meet, but by e-mails they can come with comments and we try to get a document together that everybody can accept. The competent authorities will send mail to KAJ within two weeks on which person should participate in this working group. Hopefully we can have a paper that everybody agrees on by the meeting next year.

**6. SAE/AE reporting:**

Lars Wennberg repeated the proposition from last year. After some discussion it was clarified that there has been some misunderstanding of the role of Scandiatransplant in the proposal. Again Lars Wennberg was asked to make a new document on the suggestion and have contact with all countries' competent authorities to agree on a suggestion. After that the office can be given the task of doing the programming work to implement the suggestion. In short, the suggestion is that the doctors report the necessary information to a register in Scandiatransplant. Scandiatransplant automatically transfers a copy of this information to the relevant competent authority.

**7. Plans for Scandiatransplant in the near future (Kaj Anker Jørgensen):**

KAJ told that we are now in the phase of implementing the new user interface in Scandiatransplant. This is very necessary for security and stability reason, but also for user friendliness of the system. We are eager to close down user access to the old system, and this will probably happen this year.

In the organisation there has been a lot of work performed by a working group to revise the articles of Scandiatransplant. This is mainly to bring the articles up to date with the things Scandiatransplant are doing today. When the articles were written, Scandiatransplant was a very different organisation with different tasks than it is today. KAJ also mentioned that a major issue which has not been decided is whether new Non-Nordic members can join Scandiatransplant.

**8. What has happened in the last 12 months in each country: Competent authority/board members.**

• **Main transplantation and administrative issues including the EU Directives.**

**Denmark:** Action plans for increasing donations have been made. It seems that it is worthwhile to pay more attention to the prehospital phase and increase possibilities to go to intensive care units for treatment.

Sundhedsstyrelsen is per 8 October 2015 divided up into three authorities. The competent authority for regulation and control of organ transplantation is the Danish Patient Safety Authority, "Styrelsen for Patientsikkerhed". The Danish Health Authority will still take care of action plans for increasing donations and related issues. It is the intention that both the Danish Patient Safety Authority and the Danish Health Authority will participate in NTC meeting.

Denmark has revived the pancreas transplantation programme and just made their first pancreas transplantation in many years.

**Norway:** New transplantation law has been passed. The authorities are travelling to donor hospitals and developing guidelines. The SAE/AE reporting is in place. Discussions about this have to be done with Norsk Kundskabscenter. Donor and transplantation hospitals have been approved.

Pål-Dag Line said that the southeast region of Norway has been appointed as the one that Scandiatransplant will have to make agreements with. It seems that the number of people saying no to donation in the donation situation is increasing in Norway.

**Sweden:** The inspection authority has been split from the National Board of Health and Welfare to a new body called IVO (Inspektionen för vård och omsorg). Mona Hansson from IVO gave a power point presentation of their activities. Sweden had started on a paired donation program. It is intended that other countries can join and that Scandiatransplant can play a role. It is called the STEP program. A program on uterus transplantation is continuing and there are also plans for hand transplantation. The National Board of Health and Welfare has made two publications, one is a guideline for how to increase organ donation in Sweden and it concludes that the health care sector must have an organisation model which optimise the donation and transplantation process; that education is given to all intensive care personnel regarding the donation process; and that intensive care personnel gives support to the relatives, regardless of the deceased person's attitude to organ donation. Further on these recommendations will be followed up by the The National Board of Health and Welfare on a national level. These could for example include using relevant indicators for systematic follow up. The other publication is an annual report on organ transplantation. The number has been the highest last year. An investigation will be published soon on how to increase organ donation. Oluf Högrell from

"Utredningen om donations- och transplantationsfrågor (S2013:04)" had sent a letter to the office that he could not participate in the NTC meeting, but that the group was finalizing its inquiry report to the government on how to increase the number of organ donors in Sweden. The report will be presented to the government on the 1<sup>st</sup> of October and can from the same date be downloaded from their webpage.

**Finland:** A national action plan for organ donation and transplantation has been made. They are forming an advisory board for organ donation. Procurement hospitals have appointed donor coordination teams and national level training activities have been implemented. A working group will be set up to promote live donation. On October 7th 2014, a Nordic seminar on organ donation will be held in Finland. The initiative came from the Swedish-Finnish Cultural Foundation and the Swedish advocacy group MOD - Mer organdonation.

FIMEA: There has been a seminar for all hospitals in May. Inspections will start in November in both donor and transplantation centers. Two pilot inspections have been made.

Helena Isoniemi reported that 2014 was a record year in number of donors and transplantations, and 2015 looks like it is going to be another new record. Living donation is being promoted, but there are inhibitory elements in the Finnish law. They are working at trying to change the law. All transplantations are now in the same ward and day care clinics are being increasingly used.

**Iceland:**

Leifur Bardson from the Directorate of Health had sent a letter to the meeting. It informed that the task of the Icelandic transplant committee had been transferred from the ministry of health and welfare to the directorate of health, and the directorate now was the competent authority in matters concerning organ transplantation in Iceland. However the transfer did not include funds for which reason they could not come to the meeting. The Icelandic member of the board: Margret Andresdottir therefore presented what happened in Iceland. A transplant steering group has been appointed and functions as an advisory board in the field. A website has been developed inviting people to register the wishes regarding organ donation in a central database. This database is connected to an electronic health record system at the Landspítali University Hospital which makes it possible for doctors to access the wishes of the patient regarding organ donation. A bill legalizing presumed consent was not approved in 2014, and the Ministry of Health had prepared an action plan on how to increase the number of organ donors and it is now being examined by the ministry. The EU Directive 2010/53 has now been implemented in Icelandic law. Living donor transplantations are performed in Iceland, but deceased donor transplantations are performed in Gothenburg. Gothenburg has held a seminar in Iceland on donation for hospital personnel. After this the donation rate in Iceland has doubled, but it is unknown, if these two things are connected.

**9. EU indicators exercise:**

Krister Höckerstedt told that the EU exercise of the action plan from the EU had stopped primarily because of the quality of the investigation is too low.

**10. Any other business:**

Krister Höckerstedt had asked for the subject "Organ donations and transplantations of refugees" to be discussed under this point. Pål-Dag Line gave a Power Point presentation of thoughts on this problem. He first told the NTC that ScandiTransplant has guidelines for diseased organ transplantation of non-Nordic nationals and the use of non-Nordic organs for ScandiTransplant recipients. He briefly went through these guidelines, the main point being that non-Nordic nationals whose status in a Nordic country entitles them to receive treatment under the public health care system on the same terms as national subjects in that country are eligible for organ transplantation within ScandiTransplant. Most refugees will have this status. There is however a medical problem if refugees only stay in a country for a limited time because transplantation is not a limited surgical procedure. Adequate outcome depends on long-term follow-up and medication. There are ethical obligations to ensure longevity of graft function of course towards the recipient but also towards the donor and towards all the other individuals on the waiting list. At last he pointed out that living donors require long-term follow-up. He then gave Norway as an example of the size of the problem and emphasized that when transplanting refugees these will have to accept the general allocation principles which are center based in the Nordic countries.

**11. Next meeting September 2016 (Reykjavik, Sept. 20<sup>th</sup>, 2016?):**

Will be in Reykjavik on September 20<sup>th</sup>, 2016.