

## Minutes

**Meeting No.:** 66  
**Time:** May 6-7, 2013  
**Place:** Oslo, Norway

**Participants:** The board of Scandiatransplant:

CHAIRMAN: Krister Höckerstedt, Helsinki (KH)  
SWEDEN: Lars Wennberg, Stockholm (LW)  
FINLAND: Helena Isoniemi, Helsinki (HI)  
NORWAY: Pål-Dag Line, Oslo (PDL)  
ICELAND: Margrét B. Andrésdóttir, Reykjavik (MA)  
DENMARK: Finn Gustafsson, Copenhagen (FG)

Director of Scandiatransplant:

DENMARK: Kaj Anker Jørgensen, Aarhus (KAJ)

**Leader of meeting:** Krister Höckerstedt (KH)

**Writer of minutes:** Kaj Anker Jørgensen (KAJ)

## AGENDA

### 1. Welcome:

KH welcomed everybody and said he was pleased to see that everybody could participate in the board meeting.

### 2. Agenda and format of the meeting:

The agenda and the format of the meeting was approved. KH said that he would tell about the situation in Germany under item 12: Any Other Business.

### 3. Approval of minutes from board meeting No. 65:

The minutes were approved. It was stated that the new law for transplantation in Iceland had not been passed yet. Many of the items in the minutes would be dealt with later in the board meeting.

### 4. Since last meeting:

#### a) Status at the office:

KAJ described the present situation at the office. We are in the process of hiring two new programmers. There are now four working tables in the larger room that Scandiatransplant has. A proposal from the technical department on new rooms for the programmers has been turned down, so it is still uncertain where they will be situated. The situation concerning the data protection authorities in the other Nordic countries is still uncertain. KAJ gave an overview of the meetings in which people from Scandiatransplant had participated. Newsletters and newstickers can be seen on the homepage.

#### b) To do list from last meeting:

The tasks in the "to do" list from the last meeting were in general accomplished. The guidelines for receiving data from Scandiatransplant, which are now linked to the data

request form, are not satisfactory. It was concluded that points 2 through 5 should be omitted. KAJ presented examples of such requests he had sanctioned. The board trusts that the medical director will make satisfactory assessments in such cases.

The board asks KAJ to produce a document on the security of the data in Scandiatransplant. This document is to be used in negotiations with the other competent authorities. Niels Grunnet has produced a similar document and KAJ will look into this and again try to activate the lawyer at Region Midtjylland. KAJ presented an Excel-file on number of deaths in lung and heart transplant patients in the different centers. It is obvious that there is still a problem. FG will investigate the situation to find out if the problem is at the centers or in Scandiatransplant. FG later contacted KAJ and stated that for Copenhagen the problem is in Copenhagen and it will be corrected immediately. FG will contact the other people in the Thoracic group. Until we are confident that the data are correct, we will not be able to export data to ISHLT. The layout of the quarterly/yearly report from Scandiatransplant has been criticised for some time. The board wants it divided so that you have one sheet with numbers from whole countries and another sheet with numbers from each center. The solution that the board really wants is a menu driven facility on the homepage so you can get just the number you ask for, and it would be very good if such numbers could be exported in an Excel-file, similar to the UNOS system.

**c) EU competent authorities meeting, including cross-border procurement rules:**

KH reported from the competent authority meeting in Brussels. Especially cross-border procurement was discussed. The suggestions made by the people who advise the Council would according to our judgement not be able to function. A lawyer from Austria and KH had made a document of mutual recognition of procurement teams. It was supported by the board that such an agreement should be made. KAJ was asked to send a question to all board members of how the legality and practical function was in the different Nordic countries regarding foreign procurement teams. It was concluded that Scandiatransplant needs guidelines for foreign procurement. The board should make a group for making a suggestion for such guidelines after we have an overview of how this is treated in the different Nordic countries.

**d) Cooperation with Estonia:**

The cooperation is now working well. The first offer from Estonia didn't get through because of some e-mail problems the e-mail hang for one hour before being sent. This was using a gmail account. The mail was changed to a hospital server in Estonia and there has now two times been procurement teams in Estonia. On February 22<sup>nd</sup> Gothenburg harvested both heart and lung. The procurement teams were very satisfied with the whole operation. On April 2<sup>nd</sup> a Helsinki team procured a heart from Estonia. KH reviewed the problems with non-Nordic transplantations in Scandiatransplant centers. Copenhagen had transplanted a lung to a Polish patient with a Polish donor. There had been a series of applications from authorities in Estonia and the heart surgeons in Helsinki to be able to perform heart transplants in Helsinki with Estonian donors to Estonian recipients. The board has been very critical to this situation fearing that in case of an urgent need for a retransplant, there would be a need to use a "Scandiatransplant" heart. This would violate the Scandiatransplant guidelines for transplanting non-Nordic citizens with non-Nordic organs. In the EU Directive 2011/24 on the applications of patients' right to cross-border health care it is stated in point 15: "Given the specificity, access to, and the allocation of organs for the purpose of organ transplant should fall outside the scope of this directive". On the other hand the EU Council promotes bilateral cooperation on transplantation. In the last applications from Estonia there is a plan of how the cooperation should be carried out, and it is

stated that it is for teaching the Estonians to perform heart transplants. This would be in accordance with the guidelines of Scandiatransplant on non-Nordic transplantations. Finally the Thoracic group has sent a letter to the board stating that an agreement should be made between Helsinki hospital and Estonia to have Estonian recipients transplanted in Helsinki with Estonian organs. In the letter it is stated that for the time being it is unethical that hearts from Estonian donors go to Nordic recipients while the Estonian heart patients die due to lack of transplantation. After some discussions it was concluded that KH should answer the Estonians and the Helsinki heart surgeons favouring that the transplants could be performed according to the Scandiatransplant guidelines for non-Nordic transplantation. These transplantations will be performed outside the Scandiatransplant system and the recipients should be aware of this. The situation should be monitored locally in Helsinki and in the Thoracic group. It is clear that the guidelines of Scandiatransplant are not able to overrule the laws of a country. KH will send his answer to the board members before it is sent to the applicants. The non-Nordic guidelines in Scandiatransplant had been revised as discussed on the last board meeting. The revision will be presented to the Council of representatives at the meeting in 2014.

**e. Requests from the coordinators:**

There has been three requests from the coordinators:

1. A suggestion of small changes in the form that follows the organ. This was approved by the board.
2. A request that a local coordinator participates in each organ reference group's meeting. The board approved of this.
3. There was a letter describing difficulties in organ transportation at different airports and on different airlines. The board does not think that it is a problem that the board can deal with. The coordinators should bring it up locally where they are employed. KAJ should answer the coordinators' requests on behalf of the board.

**5. Finance:**

**a) Annual accounts 2012:**

All board members had already promised to accept the accounts. Both documents were signed by all board members. It was stated that the documents should be translated into English, and KAJ promised to try to put this into effect.

**b) Discussion of separate user education budget:**

It was agreed that KAJ is responsible for how the money in the budget is used. The board trusts his judgement and he will be held responsible by the board on how the money is used.

**c) Budget 2013 & 2014:**

KAJ presented a revised budget for 2013 and a new proposition for 2014. This was approved. KAJ is of the opinion that Scandiatransplant shall not create a large fortune. Due to our special interrelation with the Region Midt we should have a fortune of about the same as one year's budget. He was of the opinion that we could use one million more than we earned the next three years and then look at the situation if the prices for each transplantation should be increased. In this case maybe one should look at the price for living donor transplantation.

**d) Compensation for board member and chairman duties:**

KAJ put forward his suggestion that the board members and the chairman should receive some compensation for their work. The reasons for this was, to professionalise the whole organisation, the increased tasks that Scandiatransplant is involved in, and especially the work concerning the EU Directives and international relations. KAJ suggested 50.000 DKK for board members and 100.000 DKK for the chairman. The

board discussed the issue but the conclusion was that the board members should not get a compensation at this time. There was unanimity that the chairman should be compensated with 50.000 DKK (~7.000 p ) yearly.

**6. Expanding Scandiatransplant. Estonian application:**

PDL reviewed work done by his group on this theme. Expanding transplant could only be done if several articles of the association were changed. A 5/6 majority would be needed at the Council meeting for such a change. PDL would present that work at the Council meeting. It was suggested that there was a minor change in article 8 of the association. This because there was a sentence which was put in due to the fact that transplantations were not done in Iceland at that time. MA will present this to the council.

**7. Council of Representatives Meeting (see separate agenda):**

It was decided to suggest Tim Scholz as leader of the meeting. The agenda was discussed and it was decided to swop point 8 and point 9.

**8. Travel and Research Grants:**

There was only one application for the travel grant. This was from Jouni Lauronen in Helsinki from the Finnish Red Cross Blood Group Service. It was decided to give him 15.000 DKK.

HI, FG & PDL were considered possibly biased, so they left the room while the Research Grant was discussed.

There were four applications for the Research grant and it was decided to split the grant so that Arno Nordin from Helsinki and Helena Isoniemi from Helsinki each received 20.000 p.

**9. Discussion of the future activities in the Sctp office:**

Many things had been discussed earlier in the board meeting. Right now we are in the process of hiring more programmers in order to accelerate moving to the new platform. We should strive at improving the working environment and the association should be aware of the scandals in Germany and Eurotransplant to avoid similar things happening in Scandiatransplant.

**10. Process of implementation of the EU Directives in each country, should each board member give a status at the Council of Representatives Meeting ?:**

Sweden has implemented the directive. They are sending SAE/AE to Socialstyrelsen. Clinicians would like to have a definition of which SAE/AE should be reported.

Finland has implemented the law by May 1<sup>st</sup>, 2013. There is still uncertainty what to report as SAE/AE in organ transplantation, but possibly it will be done likewise the tissue and cell transplantation SAE/AE is done. The competent authority for SAE reports both for organs and tissues is the same according to new Finnish law.

Denmark has approved the law and now the second edition of the ministerial order is in hearing. It is very generally formulated and will probably be followed by instructions. For the time being it seems that the only role of Scandiatransplant is to produce the yearly statistics that we produce every year.

Norway is awaiting a new law which will follow the directive, although Norway is not a member of the EU. The doctors have given an input regarding SAE/AE, but have not received any answer.

Iceland will also implement a law which will follow the directive, but this has low priority. It was decided that each board member should give a short state report on this at the council meeting.

LW was chosen to lead a group which should come with definitions on SAE/AE to report to the authorities. The board thought it would be helpful if Scandiatransplant had a uniform conception of this matter.

**11. How to count pancreas removed for organ transplantation and pancreas removed for islet isolation:**

KAJ told the board that number of pancreas islet transplantations for invoicing are the number of transplantations that the centers say that they do. It is the opinion of the board that there is a new transplantation everytime a patient receives cells from another donor. This is based on the fact that the recipient receives new foreign allo-antigens every time. There is a traceability problem. Finland is sending many pancreas' to *the Nordic Network Islet Isolation laboratory in Uppsala*, but has some uncertainty of how they are used. They can be used for either clinical purposes or for scientific purposes. It was stated that At the moment according to Finnish law retrieval of organs is allowed only for the purpose to treat a patient. We will have the same problems with hepatocyte transplantations, how to register and how to invoice. LW will discuss these problems with Lundgren and Korsgren.

**12. Any other business:**

KH gave a very short overview of the scandals in Eurotransplant/Germany.

**13. Next meeting time and place:**

Next board meeting will be on September 23<sup>rd</sup>, 2013 preceding the meeting of the Competent Authorities on the 24<sup>th</sup> of September.

Kaj Anker Jørgensen

Date: May 10, 2013