Minutes

Meeting No.: 64
Time: Sept. 17-18, 2012
Place: Helsinki, Finland

Participants: The board of Scandiatransplant:

CHAIRMAN:	Krister Höckerstedt, Helsinki	(KH)
SWEDEN:	Lars Wennberg	(LW)
FINLAND:	Helena Isoniemi, Helsinki	(HI)
NORWAY:	Pål-Dag Line, Oslo	(PDL)
ICELAND:	Margrét B. Andrésdottir, Reykjavik	(MA)
DENMARK:	Finn Gustafsson, Copenhagen	(FG)
	(Apology from Kaj Anker Jørgensen, Aarhus)	

Director of Scandiatransplant:

DENMARK:	Niels Grunnet, Aarhus	(NGR)

Leader of meeting: Krister Höckerstedt (KH)

Writer of minutes: Niels Grunnet (NGR)

The meeting was done in accordance with a slightly revised agenda distributed in paper copy at the beginning of the meeting.

1. **Welcome**
   7 present, especially welcome to FG for his first board meeting today as a substitute for Kaj Anker Jørgensen, but in the coming board meetings as the Danish board member of Scandiatransplant. FG gave a short presentation of his background: Medical specialist in cardiology/chairman of the Danish Transplantation Society since last year/responsible for the internal medicine care of heart transplantation at Rigshospitalet, Copenhagen/the primary organiser of the next Scandinavian Transplantation Society meeting in Copenhagen 2014. Then a short presentation round from each of the others being present.

2. **Agenda and format of the meeting**
   Essentials: To prepare the meeting 18/9-12 within the Nordic Transplant Committee. KH has had sick leave for 2 weeks in August 2012 in which he could not be active in relation to Sctp.

3. **Approval of minutes from board meeting No. 63**
   Approved with no comments.

4. **New Medical Director at the Scandiatransplant office in Aarhus**

KH and NGR reported on the chain of events. Ultimo June 2012 decision by NGR to stop as medical director for Scandiatransplant at October 1 or at the most convenient time nearby. This is due to workload in NGR's position as medical director at department of

clinical immunology for all blood transfusion aspects in a major part of region Central Denmark (load 50,000 whole blood units per year + analyses etc. First in June NGR phoned to KH on this wish and decision. 7/7-2012 an e-mail was sent out to the Sctp-board on the new situation. Subsequently, KH had a dialogue with the Sctp board members by e-mail and phone. This crystalized in the following:

1. None of the board members wished to move the Sctp-office from Aarhus University Hospital.
2. A very good candidate as medical director for Scandiatransplant could be Kaj Anker Jørgensen (KAJ). He accepted and negotiations with department of nephrology, leadership and HR-department of Aarhus University Hospital (AUH) came out with the solution that KAJ can work half time at the Sctp-office for Scandiatransplant, and in the remaining half time still be chief physician at Nephrology department being responsible for the kidney transplantation programme at Aarhus University Hospital. At July 13, 2012 the conditions were lightened so that NGR could have a meeting with the Sctp staff for information on the new situation (supplemented with e-mail info to those not present). The process proceeded and in September an agreement between Nephrology department and Scandiatransplant approved by the HR department, AUH could be signed by chairman of the board of Sctp, leading medical head of Nephrology department and KAJ. In the agreement it is stated that KAJ will work for Scandiatransplant on Mondays and Fridays and half of Wednesdays as normal weekly schedule. KAJ will still have his office at Nephrology department C. The agreement shall be in action from November 1, 2012.
   So, the day of change is November 1, 2012, but in the first 2 months NGR will support KAJ with knowledge, information flow etc. NGR was thanked for his 14 years as medical director for Scandiatransplant and for his activity in creating this scheduled solution. The extra costs for increasing the working time of the medical director for Scandiatransplant can be covered within the approved budget for 2012 and 2013. Otherwise the budget for 2013 can be adjusted at the Council of Representatives' meeting 2013 (remark that at the Council of Representatives' meeting in May 2012 the budget for 2012 and 2013 was approved with the following text under the table: May 2012: "Depending on today unknown extra costs due to adjustments according to implementation of the EU Directive 2010/53 (extra employed personnel and etc.) it can be necessary to regulate the budget at cost in several of the boxes above for 2012 and 2013".

5. **Sctp since last meeting (news, newsletter, homepage, office rooms, others)**
   NGR reported:
   - 3 newsletters from the office:
     June 1, especially on living donor registry in the new system and announcing closing down of the old living donor registry forms.
     June 2 on HLA-C in the deceased donor typing and relation to search, primarily relevant for STAMP patients activated by Sept. 3, 2012 due to implementing efforts before that at the tissue typing laboratories within Sctp.
     Newsletter August 2012 announcing the release of a new format of the website from August 15, 2012. In addition a new data request form was launched. The new data

request form: This was noticed by board members and had not been discussed within the board. Information on data can only be given to "members" of the Scandiatransplant association. By the chairman (supported by the whole board) NGR was ordered to get it removed from the homepage immediately. This was effectuated on Sept. 18, 2012.
The data request form could fulfill the requirements:
- for registration at Sctp-office,
- a more clear picture of who is asking for data and for which purposes, and
- if they are approved at their own transplant center, working groups, etc.

The proposal of a data request form shall now be discussed more detailed with the board members and the new medical director. The present medical director suggests that one maybe has to have two levels:
- one data request form at which you can only come in by using password, that means persons within the Sctp community
- and a more "public" data request possibility for many of the other phone calls, e-mails, etc. which the personnel at the Sctp office get as requests of many different kinds.

A suggestion is that the data request form in its present version can be sent to the board members for comments and suggestions, and then a solution can be found that can fulfill the opinion of all involved.

- Agreement between Scandiatransplant, University Hospital of Aarhus (the controller) and Central Denmark Region (the processor) in relation to management of Scandiatransplant datasystem as designated at the data protection agencies of the associated countries. A prototyp has been worked out and sent to a lawyer at Central Denmark Region. In addition a request has been made to the Danish Protection Agency to clear out how to solve that citizens not only from Denmark, but also Sweden, Finland, Norway and Iceland have data in the Scandiatransplant database administered from the Sctp office. Further will follow.
- Physical place of the Sctp-office: We are still at Department of Clinical Immunology, it has to be clarified by the new medical director.
- Possible new staff members: Set on stand-by until clarification of work load due to consequences of the EU Directive and delegation from national health authorities to Scandiatransplant office.
- Regulations of salary for two of the IT personnel have resulted in several negotiations with the HR department for salary. This is temporarily closed due to the response from them, but has to be taken up by the new medical director at a higher level in the administrative system of Aarhus University Hospital.
- Several European union affairs:
  Questionnaire: 2012 Survey on Organ Donation and Transplantation: The Sctp-office helped in filling out the questionnaires from Denmark and Sweden, but has not been involved in that from Norway, Finland and Iceland. Clearly it is a duty for the national health authorities, but sometimes they need help from the medical community within the Scandiatransplant association or from the Sctp-office on data. Also here clarifications have to be worked out with the health authorities.
- At the office: Follow-up to the Council of Representatives' meeting. Center payments for 2011 have been processed leading to some clarifications/correspondences: One fee too much (3000 DKK) had been put on the account to Stockholm, will be regulated next year. From Helsinki there was an unclarity with the counting of fee for pancreatic islet transplantations. On the invoice next year we have to write not only kidney and liver but also pancreatic islet and/or other transplantations. A request from Skåne

University Hospital concerning to put a name responsible for the activity (typically the head of the clinic), because the invoice was sent without such a notice.

- Concerning IT developments: New organ offer form in web design in test per 17. September 2012
  - Thorax interface still needs testing. Bo Hedemark Pedersen (BHP) asks for a contact person from the Thorax group or a person who can be committed to this work. FG pointed at Ulla Nyström, Gothenburg.
  - More and more people are using the living donor registry but the progress is slow. The board members are asked for activating in own centers. If they have problems, they can contact Ilse or Bo at the office.
  - Nordic Kidney registers: We have a core surface interface, but lack commitment from the community. Søren Schwartz Sørensen and Thorbjørn Leivestad have
    written a proposal to establish economy to engage a meeting initiating "data massage" and common definitions in order to be able to import the Nordic national kidney registers in the Scandiatransplant data system.
  - The application from Søren Schwartz Sørensen was approved by the board. Søren will arrange the meeting.
  - We are starting liver conversion to web these days and very much hoping to cooperate with the local liver IT-system administered by Helena Isoniemi (HI) in order to make usage of our general system interfaces.
    HI declared some difficulties in financing a webbased version, but BHP will take contact to HI. They will try to find a solution.
  - BHP has participated in a European Conference in Pisa, Italy abbreviated MIE2012, where he participated in a panel and was discussing technicalities in relation to several register functions with the purpose to use this for the modernizing of the Sctp IT-system facilities.
  - The extra fields in annex A of the Directive have been set into the Sctp datasystem, therefore Sctp IT is prepared for fulfilling the requirements of implementing fully the EU Directive at the data level for registrations of organ donor parameters.
  - Another issue is that using two donor materials to one recipient cannot be correctly registered at present in the Sctp datasystem (i.e. two pancreatic islet donors being given at the same time to one recipient). There is worked on a solution.
  - From the board members it was stated that the two tabels, one on transplant activity, and the other on waiting list figures should be modernized. The present layout has been used for some years. It is rather condensed and therefore difficult to read for those not fully familiar with how to read it. Some board members will come with suggestions for improvement, and we have to have a dialogue in how to present these data taking into consideration that within the Scandiatransplant association we have a very fine system and we have very good information on a lot of parameters, for example also exchange between centers within the Scandiatransplant association, and also concerning organs going in and outside Sctp from or to other transplant exchange organisations in Europe. The last figure is however very few organs per year.
    A more proper registration of data in relation to these very few organs being sent from a transplant center within Sctp to another place in Europe are now being worked out to secure a 100% traceability.

6. New activities in the Nordic countries

Sweden: Sjukvården is undergoing centralizing medical treatment also relevant to organ transplantation. At present there are two centers doing liver transplantations. Two centers doing heart/lung transplantations, and four centers doing kidney transplantations. It is not clear if this will continue in that way. There are also reorganisations in the national health authority (Socialstyrelsen).

Norway: PDL: Now organ donation rate for deceased donors has reached 27 pmp. A remarkable new improvement is that the refusal rate of relatives is down to 13%. The organisation "Stiftelsen for Organ Donation" has done a brilliant work in information and contact to the public also using new communication forms via mobile phones, facebooks, etc. It has been done in a proper way.

Finland: Still only one center. They are very close to start intestinal transplantations. Due to reorganisation of the health care in Helsinki (probably), there has been a decrease in the number of organ donors for transplantation in the Helsinki area in contrast to other parts of Finland. Work on improvement of this is initiated.

Iceland: MA. A proposal for a new law/regulation on the issue of presumed consent for organ donation is currently under discussion in the parliament. There has been created a homepage for kidney transplantation promoting a living kidney donation.

Denmark: FG. A case of a national TV station where they happen to be involved in rolling camera with a potential organ donor not yet been declared brain dead. Some newspapers have brought the news, but TV has not shown any programme yet.

- There has been discussion of using organ donors after cardiac death at a meeting including an expert from Holland. The meeting revealed that there are many views and very sensitive matters to discuss.
  This debate has also taken place in Sweden where the transplant law shall be changed if it should be possible to do that in Sweden.
  In Denmark, donation after cardiac death can be introduced without change of the law, but the issues are still being discussed.

Norway: PDL pointed out that organ donation is a personal right in Norway, therefore the availability of deceased organ donors is as high as it had been seen. The use of organ donors after cardiac death is not discussed in Norway nor in Finland.
A problem with cardiac death and brain death organ donors can be that messages can be blurred for the public and the society.
Thoracic people are taking up a perfusion of lungs procedure á lá Lund, Sweden to improve the quality of lung organs.

7. Process of implementation of the 2010 EU 53/Directive

5th meeting of Competent Authorities was held in Bruxelles 13-14 Sept. 2012.
26 countries were present.
<u>Finland</u> has a draft for implementing the Organ Directive, and it will soon go to the Parliament.
<u>Norway</u>: Draft with no big issues. PDL and the transplant center in Oslo have to respond within two weeks, and then the legal documents will be finalized. Still one need some guidelines for reporting SAE and SAR (Severe Adverse Events and Severe Adverse Reactions). One needs proper definitions of this. Maybe the Sctp datasystem should have a few fields for reporting the major SAEs such as cancer, transfer of infectious disease, major technical failures, unintended ABO mismatch, but not graft failure and not a lot of other issues that could be questioned. PDL will try to write some proposal for such rather simple guidelines. All the countries have systems for reporting unexpected events (UTH = utilsigtede hændelser). Proposal will then be circulated to board members and others, and

then it should probably be much more clear. The issue of 24/7 service shall be taken care of by the transplant coordinator on duty. This is a system already in action at all ten transplant centers within Sctp. PDL will also here make a proposal. For such an event

there will be a medical responsible person and some info had been given by phone, but it shall also be given by e-mail or in another written form.

8a. Work-up made and present situation in the Nordic countries

8b. EU 53/2010 Directive meeting in Brussels, September 13-14, 2012

LW will represent the board in the working group concerning improving the interface of data from NKR and Sctp.
Transplant is not included in the cross border Directive, it was clarified and stated at the EU meeting 13-14 Sept. Bruxelles. All the countries will have implemented the new organ Directive at the latest by February 2013. The indicator exercise was reported in Bruxelles. The questionnaire is in six sections. There had been exercises in 2010, 2011 and now 2012, and there will come another one next year. There is a concern what the message from these contents shall be used for, is it for creating a common European register? as somebody had suggested in the Efretos system, or what is the purpose? Sctp has to be alert not to have the present very well functioning system to be damaged.

9. The Estonian question - membership in Sctp?

PDL reported that he shall create a group to work with this issue, and it shall be pointed out with one from each of the ten transplant centers. It will probably require some meetings before a final recommendation can be made. PDL asked for names and HI from Finland, Allan Rasmussen from Denmark, KAJ from Sctp-office were put on the table. Further information later.

10. Preparing of the meeting in the Nordic Transplantation Committee Sept. 18, 2012

See separate minutes from this meeting.

11. Aspects of present Sctp structure and future challenges

KH took up a document made by NGR in February 2012. Before the ending of this year, the future working obligations for personnel at the Sctp-office, including job descriptions shall be written.
The board would like the organisation of Sctp to be as it has been known for some years now. It is a very valuable construction demonstrating trust between colleagues, centers and also between the health authorities, and those working in the medical context with organ transplantations.
Some of the issues have been discussed above (data agreement/housing/office facilities/ lawyer assistance/other things).

12. Any other business

Reporting of a German case in Göttingen and Regensburg with criminal activities. They have several problems in Germany, fx. 30 liver transplant centers compared to 9 in England, some heart centers are private clinics.
Within Scandiatransplant, if an irregularity should show up then it will be very soon detected by colleagues or the Scandiatransplant office personnel having a mutual surveillance function to secure valid, appropriate and true data.

The issue on intestinal transplantation will be taken up at the Nordic Liver Transplant group NLTG meeting on Oct. 22, 2012 in Helsinki. So far this activity is for Gothenburg and Helsinki. At the last NLTG meeting it was suggested that data managers both at Sctp-office and at the centers should have a separate meeting to facilitate proper data transfer.

HI will give a message within one week or so, if it is possible to do in connection with 22/10-12 meeting, or if separate meeting shall be created.

13. Next meeting time and place

Board meeting January 2013 in Stockholm. Day and exact place will follow. Council of representatives' meeting in Oslo on May 7, 2013 preceded by board meeting on May 6, 2013 and in the morning of May 7, 2013.
KH will come to Aarhus around November 1st, 2012.