

Minutes

Meeting No.: 62
Time: Feb. 20, 2012 at 12:00-16:00
Place: Rikshospitalet Oslo, Room B1.4024

Participants: The board of Scandiatransplant:

CHAIRMAN: Krister Höckerstedt, Helsinki (KH)
SWEDEN: Michael Olausson (MO)
FINLAND: Helena Isoniemi, Helsinki (HI)
NORWAY: Pål-Dag Line, Oslo (PDL)
ICELAND: Margrét B. Andrésdóttir, Reykjavik (MA)
DENMARK: Kaj Anker Jørgensen, Aarhus (KAJ)

Director of Scandiatransplant:
DENMARK: Niels Grunnet, Aarhus (NGR)

Leader of meeting: Krister Höckerstedt (KH)

Writer of minutes: Niels Grunnet (NGR)

1. Welcome:

2. Agenda and format of the meeting :

Agenda by Feb. 8, 2012 accepted.

3. Approval of minutes from board meeting No. 61:

Approved with no comments.

4. Since last meeting Sept 19-20, 2011 Reykjavik

- The process of job description:

Due to some incidents and a formal talk involving HR Department of Aarhus University Hospital, a process has been initiated to describe the working environment and atmosphere at the Sctp-office. A consultant from the HR Department (Psychologist) plans in the coming weeks to have a separate conversation with each one at 1-1½ hours duration at his office with professional secrecy to have an impression of the complicated organisational structure and working conditions in relation to wishes and ideas in each of the 7 individuals affiliated to the Sctp-office.

- Meeting at the office Oct. 5, Nov. 9, 2011 and Jan. 11, 2012:

Have been held in a formalised way to clarify working issues, activities, and possibility to get extra manpower etc.

- Employment of a student programmer Camilla Møller Pedersen from 01.09.2011:

Working 20 hours per week the first 2 months, after that and now 10 hours per week. She is doing a great job.

- New announcement of student help dated 12.01.2012:

This announcement has been placed at 2 different places for student jobs. We have had 1 applicant who will come to talk with all the personnel on Feb. 22, 2012. The primary working duty should be creation of a new, more professional homepage for

Scandiatransplant. The person shall preferably work in an independent way in a dialogue with the colleagues at the Sctp-office.

- Concerning the address of the Scandiatransplant office in Aarhus ?:

If several new employees are needed at the Sctp-office one needs more rooms than today. It will not be possible to get any extra square metres within the department of clinical immunology, Skejby. Due to this, there has been a search for a possible alternative to room for the Sctp personnel at the office in Aarhus. One possibility could be Incuba either at Brendstrupgaardsvej or at Katrinebjerg. Both locations are administered by Aarhus University. For the time being Dansk Center for Organ Donation is situated in Incuba, Brendstrupgaardsvej. They pay around 1/4 million DKK per year in rent for rooms plus some extra expenses at maybe 100.000 DKK. Today we pay no rent for the rooms. The situation will be followed, investigated and taken care of.

- Hearing statement to the Danish Ministry of Health dated 17.11.2011 about the new Danish law on organ transplantation as regards the EU Directive:

There had also been a dialogue with Sundhedsstyrelsen att.: Bjørn Ursin Knudsen to try to clarify the role of Sctp in relation to this new implementation of the EU Directive on Organ Donation and Transplantation. The Danish law implementing the EU Directive 2010/Directive 53/EU had been to first, second and third treatment at the Parliament and passed with a great majority on Feb. 9, 2012. The text of this new law is rather broad in expressions and gives the mandate to Sundhedsstyrelsen (National Board of Health) to implement its content (giving possibility to delegate several functions to the Scandiatransplant organisation). However, we have not yet seen a proposal for an agreement between the National Health Authority and Scandiatransplant to clarify what the duties are for the National Health Authority and what duties are for the Scandiatransplant office and the Scandiatransplant association.

- Hearing statement to the Swedish Health authorities - Socialdepartementet - dated 22.11.2011. Genomförandet av EU-direktivet om mänskliga organ avsedda för transplantation. <http://www.regeringen.se>. ISBN 978-91-38-23627-7:

MO reported that there had been a round between Socialdepartementet and the Transplantation Centers in Gothenburg, Stockholm and Uppsala; one registry is wanted, it is the overall intention to make it not complicated and it is the wish from the Transplant Centers to keep on using the Sctp cooperation. These discussions were in late autumn 2011. After that there had been a meeting December 12, 2011 at Socialstyrelsen, Stockholm, see separate minutes from this meeting.

- NOU (Norges offentlige utredninger 2011:21 med titlen: Når døden tjener livet, Et forslag til nye lover om transplantasjon, obduksjon og avgivelse av lik).

www.regjeringen.no:

PDL (Pål-Dag Line) reported that Helsedirektoratet is very positive to let Sctp do the registrations known as it is today. However, it is a law department taking decisions. PDL is in contact with them and some work with 2 lawyers from the law department has recently taken place. PDL will inform the board. It is the intention to avoid double registrations.

HI (Helena Isoniemi) reported from Finland that in December 2011 there had been a meeting in the Ministry; no new law will be created as a consequence of this EU Directive. At present Helsinki University Hospital has a register from which is also reported to the Sctp registries. Final decisions have not yet been taken.

- Meeting with lawyers from Region Central Denmark on 28.11.2011

- Meeting in Stockholm on 12.12.2011 with Health Authority representatives:

See separate minutes from this meeting (Enclosed).

- European Board of Transplant Coordination (BTC) / UEMS. Sctp's representant i styrelsen:

During the chairmanship of Arnt Jakobsen, Kathe Meyer from Oslo came in as a representative from Scandiatransplant to this European group of coordinators. Normal practice is that a representative is there for 4 years. At present it is Kathe Meyer, Oslo. Carola Schaumann is suggested as a substitute, and when the 4-years period finishes then it is planned that Carola Schaumann will go in as representative from Scandiatransplant. In January 2010 Kathe Meyer was elected for the executive committee as treasurer. A meeting is planned in Budapest on Jan. 20, 2012. There is an application for refunding flight ticket and 2 hotel nights. This is approved by the board.

5. What's new in the Nordic countries:

Apart from what is said above: Implementation of the EU Directive and the role of the relation between national health authorities and the Scandiatransplant office and organisation:

If the great majority agrees on a minimum dataset then it will be that defined in Scandiatransplant fulfilling criteria in annex a of the directive.

A dark horse is SAE (serial adverse events) and SAR (Serial adverse reactions) which the national health authority shall report according to the EU directive. In Denmark one has a system for so-called unexpected events in the health care system (utilsigtede hændelser). The directive states that informed consent from patients has to be obtained to send data to a register in own or another country. Norway has had this system for some years with written statement from all recipients and living kidney donors in which they accept that data is sent to the Sctp register in Denmark. Informed consent in a written way is not systematically documented in Denmark and Finland today, but of course there is a consent from the patient when they are set on a waiting list for organ transplantation. In Sweden the informed consent is part of quality assurance of the health care process. If a study has to be performed or a biopsy has to be taken then the informed consent is documented in a formal way. But these say nothing on the Sctp data register today.

Summary:

Issues of informed consent

Issues of SAE and SAR have to be clarified in the expected agreements between national health authority and Scandiatransplant for each of the 5 countries now collaborating in the Scandiatransplant association.

Other news:

A patient from the transplant center in Aarhus had been kidney and pancreas transplanted in Oslo based on agreement between the 2 transplant centers involving back-delivery in the future which also should imply training of surgeon from Denmark in pancreatic transplantations.

Other issues:

- A situation of fewer physicians in Reykjavik in the area of organ transplantation; still cooperative work with Gothenburg.
- Oslo, Norway now nearly complete schedules for the generation change of the surgical teams.

6. The implementation of the 2010 EU 53/Directive

- in Denmark, Finland, Norway and Sweden – and Iceland**
- impact on the Sctp organisation and office.:**

See what has been mentioned above. There will be a follow-up meeting between the Sctp organisation and representatives of the national health authorities at the national health authority in Copenhagen on April 16, 2012 at 12.00-16.00.

7. Transplantation figures for 2011 and Waiting list statistics 01-JAN-2012

- Annual Accounts 2011:

All the figures were looked at and discussed by the board. 2011 gave 436 utilized deceased donors. This should theoretically give 872 kidneys, but in fact 779 deceased donor kidneys were transplanted. Why this gap? Several of the board members replied that some of the organ donors are only donors for for example liver. But there are other causes. The board asks for a list of what happened to the organs not used. A question to the Sctp-office/registers. What has been documented in the Sctp database? Then there is a wish for a new design of this very compact scheme on 1 page with all the transplantation figures for 1 year. One wish is to make 1 sheet per organ plus some graphical presentations.

Re: Waiting list statistics for the year 2011 per 01 January, 2012. The total sum of patients died while waiting on waiting list for an organ transplant (all organs) was 118 in total. 510 patients were at the inactive kidney waiting list while 1229 on the active kidney waiting list by the end of 2011. The scheme for transplantation fees 2011 was presented and discussed and it will give rise to an expected income of 4.510.600 DKK. A total of 36 representatives shall be appointed for the next year, the same as the year before, but with some changes (1 more from Oslo and Stockholm and 1 less from Gothenburg and Skåne). In the annual accounts for 2011, from the accountant KPMP (statsautoriseret revisionspartnerselskab) there was a printing error on page 9 and 3 of the hospitals ask for corrections in the naming of the hospital. The annual accounts were approved and signed by all members of the board in 3 copies. There was a discussion of the fee for 2012 and 2013. The fee for 2012 has already been decided on at the Council of representatives' meeting 2011, but can of course be changed at the meeting in May 2012.

The board decided to give an economical bonus to Bo Hedemark Pedersen for his extraordinary effort (lowering IT licenses etc.). NGR shall investigate possibilities.

8. The Scandiatransplant IT-system and way of communication of organ offers:

During autumn 2011 a new telephone system was set in use at Aarhus University Hospital. After that it was not possible anymore to use the automatic fax service which had functioned for some years after we let down the standard fax solution.

A new system has been created due to extraordinary efforts by Bo and Ilse where Scandiatransplant transplant centers via an e-mail and by our new system will generate SMS to a long list of transplant coordinators at the transplant centers. However, there have been some errors, but they should be corrected and eliminated now together with extra surveillance of the system.

Friday, Feb. 10, 2012 we had another experience:

A phone call from Gothenburg, subsequently from Oslo that they could not get in touch with the Sctp-datasystem. The situation was solved by Bo. It was due to the IT-department at Region Central Denmark. Due to an announced threat from a Swedish hacker "pirat bay" and the hacker group "anonymous", the IT-department had closed several ip-addresses including those used by the Sctp. Due to a mistake these IT-department had not given any information to the Sctp-office on this! The error was corrected in the afternoon on Friday 10, 2012.

9. Travel Grant applications 2012 (6 received):

1. Lars Bäckman: 12.000 DKK
 2. Kristine Andreasson: 25.000 DKK
 3. Emma Høgstrøm: 15.000 DKK - She will be asked to select 1 of the 3 travel possibilities.
 4. M. Lempinen: 7.500 DKK
 5. No grant
 6. Lonnie Rasmussen 2 nurses 3 days in Oslo: 15.000 DKK
- A total of : 74.500 DKK granted.

10. Research Grant applications 2012 (5 received):

After careful judgements and evaluations project No. 2 with the principal investigator Lars Bäckman was chosen. This project integrate all transplant centers within Sctp. The project has been approved by the local ethic committees in the different countries. The project: "Analysis of the true incidence of post-transplant malignancies in renal transplant recipients. Initiation of a Nordic project on post-transplant malignancies". It will be supported with 20.000 €.

Then the board discussed the amount given for research purposes. The debate ended in the conclusion to raise the sum to 40.000 € per year where the board has the possibility to give it to one project or to divide it to more than 1 project.

11. The Estonian question. See attachment:

Estonia has more than 1.4 million inhabitants. They have built up a team system in Tartu. Tartu University Hospital does the transplantations, although Tartu now has been certified by EFI and fulfilled other demands for a membership of Scandiatransplant. It is argued that it should be the Estonian organ exchange center which need an official paper that it is a national transplant center and not only a center for Tartu. KH will write to Estonia and the Ministry of Estonia a letter circulated to members of the board for comments at first on the opinion that Scandiatransplant needs an official paper, that Tartu University Hospital is the Estonian organ exchange center, and that it is a national transplant center. The issue also has to be discussed in the different groups within Scandiatransplant and with the owners, i.e. the transplant hospitals.

12. Newsletters from Scandiatransplant:

Last one was from September 2011. One newsletter probably planned for the spring 2012.

13 The work tasks at the Scandiatransplant office:

Due to the fact that the volume of the working load due to implementation of the EU Directive 2010/53/EU is not clarified yet much more will be known in approximately 6 months time. At that time by the end of this year 2012, the work load will be known and therefore the board looks at it as they have the responsibility to elaborate a contract with each individual employee at the Scandiatransplant office in Aarhus. Within this contract a job description will be included.

14. Scandiatransplant participation in EU and EC meetings:

Next meeting is March 1 and 2 in Brussels with participation of KH, NGR and Frank Pedersen.

15. Changes in the Scandiatransplant Board at the Council meeting, May 9:

Sweden has to decide who shall be the next board member from Sweden because Michael Olausen then has been a board member for 6 years.

16. Other subjects/information:

KH will come to the office in Skejby on March 6, 2012 for discussion of especially strategic issues with all the employees at the office.

The annual meeting in the Nordic Transplant Coordinator Group is scheduled to be in Aarhus in mid-April 2012. The elements were discussed. It was stated that if there should be a course then there should be a programme for the course. At the meeting, the board decided to follow the previous set of rules for financial support, but after the board meeting it was clarified and decided that Sctp will give financial support (travel, 1 hotel night) for each person from each transplant center within the Scandiatransplant association. The meeting will then be a 2-day meeting consisting of the normal meeting of the transplant coordinators' group supplemented with course activities to train the coordinators in proper use of the Scandiatransplant registers and to do correct registrations in the Sctp database.

- NGR and Susanne Sønder have been working with documentation and clarification for the administrative part of the Efretos project. Some of the administrators have difficulties in understanding that Scandiatransplant is an association under Danish law, not VAT-registered and not allowed to deduct VAT.
- A case in Denmark where a case of a deceased organ donor with no sign of malignancy at the time of transplantation gave organs to several recipients. Subsequently, it was realized that the organs had transferred very malignant tumor cells. Such a case is a typical SAE (serious adverse event), and when the EU directive is implemented in all the Nordic countries there will be or shall be created a system for reporting and registration of such SAEs.
- Feb. 6, 2012 there was a meeting in the Tissue Typers' Group in Uppsala, Sweden. The group is very seriously working with several issues, especially the STAMP programme and the consequences of this for the tissue typing laboratories and for the database and the registrations.

17. Any other business:

NGR gave a presentation on aspects of the present structure and future challenges of Scandiatransplant. Sctp today is 5 countries, 10 transplant centers, 30-50 transplant coordinators plus other affiliated persons organised with a board with chairman//Council of representatives, and a number of reference groups: Liver/Thorax/Kidney incl. pancreatic patients/Tissue Typers/STAMP/Transplant coordinators/Prevention of infectious diseases.

The database and the office is situated in Aarhus at Aarhus University Hospital with 7 persons affiliated who due to part time affiliations will give a total of approx. 4.6 man years. Adjustments or issues to be formalized in written agreements in the time to come:

- Agreement with Aarhus University Hospital (AUH) on services on account/HR etc.
- Agreement with Region Central Denmark on data management
- Agreement with Health Authorities (DK/FIN/IS/S/N)?
- Rent agreement for housing/office facilities etc. if outside AUH
- Lawyer assistance on an hourly fee basis?
- A future working obligation for personnel at the office has to be clarified (i.e. service functions/educational issues/new programming issues/administrative functions/international functions and relations.
- The future of Sctp as an organisation has to be evaluated and clarified by statements from the board and the council of representatives.

18. Next meeting time and place:

Board meeting on May 8 and May 9, 2012 Reykjavik.

Council of representatives' meeting May 9, 2012 at 13.00-16.00 Reykjavik

Board meeting in Helsinki September 17, 2012 with Nordic Transplant Committee meeting on September 18, 2012.

Writer of minutes: Niels Grunnet