

Nordic Transplant Committee

/ Nordic Transplant Committee / Minutes meeting No. 16 Sept 20, 2011 Reykjavik

Nov. 1, 2011

MINUTES OF MEETING

Meeting No: 16th meeting in the Nordic Transplant Committee

Time: Tuesday, Sept. 20, 2011 at 08.00 - 11.00 a.m.

Meeting place: Reykjavik

Meeting participants:

National Health Authority representatives:

Erik Kreyberg Normann (Helsedirektoratet) leader for Department for Specialised Health Care in the Directorate for Health. Erik.Normann@helsedirektoratet.no

Per Fauchald, (Helsedirektoratet), Norwegian Directorate for Health, Department for Specialised Health Care, Oslo. p.fauchald@c2i.net

Charlotte Möller, The National Council for Organ and Tissue Donation (Socialstyrelsen Donationsrådet), Stockholm. charlotte.moller@socialstyrelsen.se

Dr. Jón Baldursson, Ministry of Welfare, Iceland. jon.baldursson@vel.is

Bjørn Ursin Knudsen, Sundhedsstyrelsen (Health Authority), Copenhagen. bjk@sst.dk

Helle Haubro Andersen, The Danish Centre for Organ Donation, Aarhus, Denmark. hellanse@rm.dk

The board of Scandiatransplant:

(KH) Krister Höckerstedt, Helsinki

(HI) Helena Isoniemi, Helsinki

(LW) Lars Wennberg, Stockholm

(PDL) Pål-Dag Line, Oslo

(KAJ) Kaj Anker Jørgensen, Aarhus

(MA) Margret B. Andresdottir, Reykjavik

Apologies received from:

(SM) Sveinn Magnússon, Ministry of Welfare, Iceland. sveinn.magnusson@vel.is

Medical director, Scandiatransplant:

(NGR) Niels Grunnet, Aarhus

A G E N D A

1. Welcome

Welcome to Reykjavik, Iceland by Jón Baldursson and by the chairman of Scandiatransplant KH.

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

Chairman of the meeting KH and writer of the minutes NGR.

3. Approval of minutes from meeting No. 15, 2010:

Approved. KH gave a short summary of the issues.

4. Additional issues for the agenda from the participants:

Especially the implementation of the EU directive 53/2010 by August 2012 in each country.

5. What has happened in the last 12 months in each country:

Denmark: Helle Haubro has written a summary of two pages which is enclosed to these minutes. One can especially mark that part of the problem to get deceased donors is that the doctors turn down potential donors. The three centers in Denmark have especially increased living kidney donor transplantations.

Norway: Erik Kreyberg Normann (EKN) reported that there had been eight episodes on the TV2 channel in Norway on organ transplantation with a very positive effect that has now increased awareness in the population of organ transplantation. Norway has come to bigger than 40 pmp deceased donors which is remarkable. Oslo has performed 50 towards 38 liver transplantations in the same time period: An increase. Fewer deferrals from relatives have been observed. Norway is still working on a new transplantation law which is planned to integrate the EU directive recommendations. In Norway there has been a reconstruction of the hospital organisations, therefore there has been a worry if there are enough donor hospitals in the future. This is a challenge which shall be faced in Norway in the coming time. Per Fauchald (PF) reported that there had been a little decrease in the number of living kidney donors. Pål-Dag Line (PDL) reported on the boost in Norway in organ transplantation placing Norway as number one in the Nordic countries in this area. KH applauded this development in Norway where deceased donors retrieved has substantially increased the number of transplanted recipients which is not always the case in all European countries. Norway has also set up a DRG financing of organ donation to have hospitals refunded for this activity by the state.

Sweden: Charlotte Møller (CM) reported a decrease for the last three years in the rate of deceased donors. She hoped that this is now stabilised. There has been less identification of potential deceased donors, which points to that something is going on in the intensive care units of Sweden. The problem is to continue treatment until brain death has been diagnosed instead of stopping all treatment activity. The public in Sweden is very positive towards organ donation. In a poll nine out of ten Swedish citizens declared willingness to donate organs in case. Sweden has had a big debate on treatment of seriously ill patients.

SKL (The Swedish Association for Local Authorities and Regions) recently has adopted an action plan for promoting organ, tissue, blood and cell donations. This action plan will reach full potential in 2012- 2013. The action plan focuses on finding obstacles and possibilities within the health care sector and will strengthen the education for health care personnel.

Finland: HI informed that a year ago, Finland had a new transplantation law where the consent was changed from informed consent to presumed consent. Since then there had been a little increase in the donor frequency, but things take time. An aspect of the new law is that the next of kin cannot deny organ donation if the deceased person earlier on had declared willingness to donate organs. That is a learning process in Finland to implement these new conditions. Concerning implementation of the EU Directive to the existing law there had been a meeting with the transplant people and representatives from the Ministry and Health Authorities. For Helsinki, since February 2011 all organ transplantations are now performed in the same hospital area in Helsinki with coordinating and common operating theatres.

However, the wards with beds are placed with a little longer distance in the hospital area. KH: "Seven countries have now presumed consent in EU, the main thing is to dedicate organ donation hospitals and the new law in Finland has now pushed it in a more obligatory direction for these donation hospitals to fulfil their role. For the last ten years an international Donor Action programme has been functioning in 60% of the hospitals, which themselves check the number of deaths, number of brain deaths, number of potential and number of utilized deceased donors. In Finland there is still a huge potential of donors that are not realized deceased donors. The main problem is that suitable potential organ donors are not identified (like in Denmark). However, when a potential donor is identified, the process is running very efficiently in Finland compared to six other European countries (ESOT 2011).

Iceland: Margret Andresdottir (MA). Iceland has a co-work with Gothenburg concerning deceased donor transplantations. The transplant coordinators in Iceland are in direct contact with Gothenburg. There are not many brain death individuals in Iceland, therefore there is a limited number of deceased donors. There is a rather high transplant frequency using living kidney donors in Iceland. Intensive care beds (app. 25 in total in Iceland) are located in three places, two of them in Reykjavik and the third in Akureyri. Only minor corrections during the last year concerning organ transplantation in Iceland.

6. Data collection and registrations today in the Scandiatransplant datasystem:

Several registers exist today for example Finland, Sweden and Norway are sending data to Opelz-Registry in Heidelberg on kidney transplantation. From Finland data on liver transplantation are in addition to Sctp's system also sent to the European Liver Transplant Register in Paris, being a voluntary organisation and 93% of all European liver transplant centers send data to this register. The Sctp system includes all organs; kidneys, livers, pancreas, hearts and lungs are also registered. The database of Scandiatransplant is based in Aarhus and data registered in the system mainly by the transplant coordinators at the 10 transplant centers within the Scandiatransplant cooperation. From the register there are quarterly reports on transplantation activity and waiting list statistics published on the homepage, and in addition some ad hoc extracts are done. We need to have a definition of the minimum data set for each organ to be registered from all centers within the Scandiatransplant cooperation. Charlotte Møller (CM) stated that via the Sctp system we can prove that recovered organs are used for transplantation. That is a praise of the system.

7. EU Directive on Organ Transplantation

- a. 2011 indicators exercise for organ donation and transplantation "Common understanding on allocation systems, waiting lists and health outcomes". 14 out of 27 member states have answered this questionnaire before a meeting in Bruxelles on July 13, 2011. Finland was one of the countries having answered the questionnaire.

The EU-directive Action Plan Survey Nr 2. Answers from the five Scandinavian countries. Discussion on future strategy of the Action plan. Is there a need/possibility for a common strategy in this issue for the five Scandinavian countries?

The issues and the status of this will be discussed at a meeting in Bruxelles Sept. 26-27, 2011.

On August 4, 2011 Krister Höckerstedt sent an e-mail and the questionnaire to our contact persons in the Health Authorities and to the board of Scandiatransplant to catalyse an output of this inquiry from EU to member states on organ donation and transplantation data.

The EU-directive Action Plan Survey No 2 had a questionnaire which was answered by Finland, Denmark and Sweden, not relevant for Iceland, and Norway got the questionnaire rather late. The answer from Finland covered remarks that in every organ some mandating exclusion criteria exist plus some variable criteria. The questionnaire on allocation was difficult to answer. In Scandinavia, one first search in the Scandiatransplant system for kidneys to see if there is mandatory exchange obligation and then locally allocation criteria is in action. There was a comment on this from Denmark to the questionnaire. The allocation criteria are mainly immunological and waiting time based. It was stated that medicine is not engineering. EU would like to get an impression of what is the present situation throughout Europe. The purpose with the questionnaire seems to be an impression of what would be feasible to know.

The Nordic countries have survival data on kidneys in the uremic registers. In Finland follow-up data of all organs are in addition listed in the official Transplant Registry of the Helsinki University Hospital. It was questioned what will Norway do in relation to EU-directive 53/2010. A hearing phase is going on in Norway with production of drafts to find out what data required by the Directive would be possible to delegate to Scandiatransplant and what would not. The Directive's Annex A is mandatory and the participants thought that it could be ok with mandatory reporting. In the present Sctp data system we lack indication of neoplasia and medical addiction in the history; it is wished from the participants that if it can be put into

the Scandiatransplant data system, it should be simple to set up for example with neoplasia yes/no/unknown. Lars Wennberg (LW) stated that in autopsy studies prostate cancer could be detected in approx. 12% of the deceased donors with no knowledge of this before the autopsy (Yin M. et al, Journal of Urology, March 2008: Vol. 179: 892-895). At the time of decision such statements on donor health can only be to the best knowledge available. From Sweden it was stated that they can see the advantages in using the Sctp data system for reporting to EU, but that lawyers in Sweden are very concerned if it is possible and not against the law to send data on the Swedish patients to a register in Denmark. To clarify this it is decided to have a meeting in Stockholm in this autumn 2011 with lawyers present to clarify what register shall be established to fulfil the EU directive and to clarify the permission of the Sctp data system in Aarhus, Denmark. The purpose is also to check what relevant data is in the Sctp data system today.

Participants should be the participants of this meeting and any lawyers and health authorities of the Nordic countries. It is important that the Sctp office personnel is present, too.

b. Discussion on data in the EU Directive 53 Action Plan, Annex B.

According to the Directive the data in Annex B are not obligatory. This was held as a positive issue by all participants.

c. Implementation of the EU Directive in the legislation of the three member states and Norway and Iceland.

In Sweden a new law is needed. In Denmark a new law is needed. Finland has a new law since autumn 2010, so they will implement the new issues from the EU directive in the existing law complex. In Norway, they are working with a new law. In Iceland, it will be implemented in the existing law.

8. Activities within the Council of Europe (CoE) and others:

- **“The Fourth edition of guide to safety and quality assurance for the transplantation of organs, tissues and cells” was published 2011 (ISBN 978-92-871-7027-9).**

From Sweden it was asked: Are you happy with this? Because not all transplantation people know the details stated in that. From Norway, it was stated that the guide is with the purpose to rise the level in the countries that do not have transplantation tradition with good clinical practise.

- **The Efretos (European Framework for the evaluation of OrganTransplants) project ended in May 17, 2011.**

It was led by Arie Oosterlee and Axel Rahmel. The main goal was to create a common registry of registries for all organ donations and transplantations in Europe. Sctp has not been in favour of such a Pan-European registry, and actually Sctp participated with a minor part in the definitions of specific issues on kidney and liver transplantation. It is the impression now that there is "fight" of who shall decide in Europe with respect to organ donation and transplantation and some would like to create common European registries. KH gave a formal power point representation of the elements of Efretos in three tiers (levels of data): Data collection extended/Data set and under that a minimum data set supplemented with basic data set). In the minimum data set for kidney for example the following number of parameters were defined for tier 1) 40, tier 2) 29, for tier 3) 109.

In April 15, 2011 a letter was sent from KH to Efretos on behalf of the Scandiatransplant board stating some recommendations and stating some questions to be answered in relation to such an initiative. It was asked what happens now after Efretos? At the EU in Brussels it is clear that they will only give money to projects not to implementation of for example Efretos. Some in Eurotransplant especially are still working on how to implement the Efretos.

Participants of the present meeting stated that there is no reason to increase the present work load. Very good data on follow-up already exist in Scandinavian countries, although some further specifications need to be done.. There are big differences between UNOS taking care of one country (USA) compared to Europe with a greater diversity between the states.

9. Rapid alert systems (EU office):

At the EU office they have created a new activity where they send out messages on new infections for example West Nile virus and the outbreak profile. It is necessary to have a

balance of judgment of the real risks in connection with organ transplantation and the summary can be that one has to take into consideration some additional risks in some cases when you have a potential organ donor. We have guidelines from a working group of infectious diseases under the Scandiatransplant organisation, which is always rapidly consulted for adjustment of the recommendations.

10. Any other business:

It was concluded that an extra meeting with the present participants and Sctp office members plus other relevant national experts is organised this autumn in Stockholm. Suitable preliminary dates suggested were November 21, December 5 and December 12. After additional checking of the dates has been done an invitation will be sent of by the chairman. Two specific issues will be discussed:

- 1) Is there a will and a possibility in the Nordic countries to have a similar list of data to be included in the respective national registries required by the EU-53 Directive?
- 2) Would it be feasible to continue the system of collecting and sending national and center data respectively to Scandiatransplant, which transforms the data into a form requested by EU?

11. The next Annual meeting will be in September 18th, 2012, presumably in Oslo, Norway