

Nordic Transplant Committee

/ Nordic Transplant Committee / Minutes meeting No. 17 Sept 18, 2012 Helsinki

Oct. 4, 2012

MINUTES OF MEETING

Meeting No: 17th meeting in the Nordic Transplant Committee
Time: Tuesday, Sept. 18, 2012 at 12:00-16:00
Meeting place: The Ministry of Social Affairs and Health, Department for Social and Health Services, Meritullinkatu 8, Helsinki, Finland.

Meeting participants:

National Health Authority representatives:

Liisa-Maria Voipio-Pulkki, Ministry of Social Affairs and Health, Health Department, Finland. liisa-maria.voipio-pulkki@stm.fi (partly present)

Timo Keistinen, Ministry of Social Affairs and Health, Health Department, Finland timo.keistinen@stm.fi (partly present)

Jorunn Svendsen, (Helsedirektoratet) Norwegian Directorate for Health, Department for Specialised Health Care, Oslo. jsv@helsedir.no

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

Eeva Leinonen, Finnish Medicines Agency. eeva.leinonen@fimea.fi

Tesi Aschan, The National Council for Organ and Tissue Donation (Socialstyrelsen Donationsrådet), Stockholm. tesi.aschan@socialstyrelsen.se

Maria Åberg Sjölin, The National Council for Organ and Tissue Donation (Socialstyrelsen Donationsrådet), Stockholm maria.aberg-sjolin@socialstyrelsen.se

Tore Ryberg, Sundhedsstyrelsen (Health Authority), Copenhagen. try@dkma.dk

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

(FG) Finn Gustafsson, Copenhagen

(MA) Margret B. Andresdottir, Reykjavik

Apologies received from:

Kaj Anker Jørgensen, Aarhus (KAJ)

Medical director, Scandiatransplant:

(NGR) Niels Grunnet, Aarhus

The meeting was performed according to the agenda sent to the participants in advance.

1. Welcome

Chairman of the board Krister Höckerstedt welcomed to this meeting between representatives of the health authorities in the five Nordic countries and the board of Scandiarttransplant.

Then director Liisa-Maria Voipio-Pulkki from the Ministry welcomed all to this meeting and gave a short summary of what is going on in the Finnish Health Care System for the time being: Health care reform is planned with many discussions and political debates (municipality versus ministry directed). Finland has five university hospitals and discussion in Finland is as in other European countries going on which treatment shall be offered at university hospital level or at basic levels throughout the country. The administrative system in Finland obey EU, but there are several challenges and questions to which Finland has to take its own decisions to some of them. Major changes are expected to come and in the meantime hot political issues are discussed. Some controversial and some with immediate consensus. A civil servant, a lawyer in the ministry, shall be appointed to take care of implementation of the EU directive on organ donation and transplantation. The implementation process is expected to be fulfilled within less than half a year.

Then there was a short presentation round of each of the participants.

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

Chairman was Krister Höckerstedt (KH) and writer of minutes was Niels Grunnet (NGR).

3. Approval of minutes from meeting No. 16, 2011

Accepted with no comments. Last year has been special that we have had two meetings apart from the regular annual meeting Sept. 20, Reykjavik (in total three meetings). There had been meeting in Stockholm on Dec. 12, 2011 and meeting on April 16, 2012 in Danish Health and Medicines Authority, Copenhagen. The minutes of these two meetings were also dealt with, especially the last one from April 16, 2012. Approved with no comments apart from the remark that Eeva Leinonen is not lawyer but head of the medical inspection in Finland. Jon Baldursson, Iceland has a new e-mail address: jon@landlaeknir.is.

4. Additional issues for the agenda from the participants

None.

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

• **Main transplantation and administrative issues**

Denmark

Norway

Sweden

Finland

Iceland

From Sweden, Lars Wennberg reported no major changes. Some centers think of doing new forms of transplantation and there is a debate on the number of transplant centers, but so far Sweden has the same number of transplant centers.

Tesi Aschan reported that they had worked with some unclear declarations in the directives, but the situation is expected to be cleared up within the next months. Maria Åberg Sjølin worked on communication, a new webpage, especially dealing with organ donation, initiatives in relation to Facebook to get in touch with especially young people in Sweden is also worked with. She reported that Charlotte Möller had left Socialstyrelsen, and that replacement for her will be pointed out soon.

From Norway, Pål-Dag Line (PDL) reported on the increase of the number of deceased donors, but the major new improvement is that rejection frequency from relatives is down to 13% in the last months, with an average of 18%. There had been a good dialogue with Helsedirektoratet on other issues in relation to organ transplantation. The continued work with action for getting deceased organ donors, one has not to lay down on the success but continue the process of working with these issues. Especially Stiftelsen for Organdonation had done a tremendous and very successful work towards the public in Norway.

Thoracic surgeons are looking into better lung preservation to condition lung organs for transplantation. Jorun Svendsen reported that all donor hospitals are in place and demonstrated a lot of motivation. The lawyer Kari Steig (not present) has worked hard on the legal documents in relation to implementing the content of the EU organ directive. Per Fauchald added that concurrent with the increase of deceased organ donors there has been a little decrease in the living organ donors, but all are waiting for the new transplant law and hope that the frequency of living organ donors can be brought back to an old standard for Norway.

From Denmark Finn Gustafsson reported no major changes in the level of transplant activity. Aarhus and Oslo have had a concrete co-work on transplantation with pancreas to a Danish patient and this will probably lead to reopening of the pancreas transplant programme in Denmark. In the transplant society and in the professional transplant community there had been discussions on using donors with cardiac death for organ transplantation, however there is no consensus at the time being so the discussion and investigations in this field will continue for some time before it can be clarified if this is a possibility to increase the number of organs for transplantations (such a discussion has also taken place in other of the Nordic countries, i.e. Sweden and Norway, but no decisions are made so far).

Helle Haubro Andersen reported on the annual report from 2011

[Encl in Danish DCO.pdf](#). In short, in 2011 29% of relatives said no to deceased organ donation. The investigation revealed that in 10% of cases in intensive care units ICU, potential organ donors were not detected. The main reason for this is that doctors at ICU had not identified potential organ donors to such a level that they contacted the transplant center for further evaluation to make the decision if this could be a deceased organ donor if all criteria were fulfilled. The next step will be to address the organisation at the hospital levels. Representatives from Danish Center for Organdonation visited Norway in spring 2012 to learn and be inspired to improve the activity in Denmark. From other meeting participants it was added that potential deceased organ donors were not evaluated in relation to possible organ donation during their way from arrival at the hospital until they are placed in the intensive care unit.

Bjørn Ursin Knudsen added that there had been a discussion in the Parliament on presumed consent. The discussion is not finished, and no decision taken yet.

From Finland Helena Isoniemi reported that there had been an increase in living organ donor kidney transplantations, but one is still working on that. There is an improvement in the pancreas programme. The condition with presumed consent had now been active for 2 years in Finland.

Moving transplant activity in Helsinki from a separate area to the big hospital Meilahti area created a dramatic fall in the number of realized deceased organ donors from the Helsinki area, but after one year with decline it is now improving again and efforts set in to not only have the usual level from hospitals outside Helsinki.

Eeva Leinonen reported that no formal system of inspection with regard to organ transplantations has been set in system, but they have experience from Blood and the Tissue and Cells Directives and expect that some form of inspection also will be set up in relation to organ transplantation.

From Iceland Margret Andresdottir reported that they have their living donor kidney programme in Reykjavik, and they have contract with Gothenburg, Sweden for deceased donor transplantations of several organs. The minutes of this meeting shall be sent to Jon Baldursson (see the correct e-mail).

NGR was asked to present a review of the transplant activity within the Scandiatransplant association for 2011. Ten dias were shown (enclosed) [dias2011sorted11.ppt](#) . More dias can be seen at Scandiatransplant homepage www.scandiatransplant.org. It is remarkable that more than 1800 organs are transplanted during a year within the five countries. In total 120 patients had died on the waiting lists for different organs. Very few organs from deceased donors are sent outside the five Nordic countries per year. It is in the magnitude of five or less being sent from the whole Scandiatransplant area to another transplant organisation within Europe and the number of organs received from outside Scandiatransplant countries from European transplant organisations/countries is at the same magnitude. So available organs for transplantations are in the late 90ies percentage finding a recipient within one of the transplant centers in the five Nordic countries being member of the Scandiatransplant association. As seen from one of the dias there is a remarkable exchange of organs between transplant centers within the ten Scandiatransplant transplant centers, see the slide. The exchange of organs has been created by the transplant community by defining rather simple rules for mandatory exchange and for "back delivery" systems and for favouring critically ill patients to get an organ from either own country or one of the other countries within Scandiatransplant giving reasonable waiting time. The trust between the centers and between all employed in the transplant community has created a very solid system and with a symbiotic effect due to the fact that having a background population of approx. 25 mio. people, one can treat very special individual patients that may be not could have the opportunity to be treated if one only was looking at the population of own country.

Again it was pointed out the remarkable results created in Norway with a world record level of kidney transplantations per million population, combining using living and deceased organ donor kidney transplantations.

6a. EU Directive on Organ Transplantation.

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

Transplantation in Finland. The ministerial documents have been in draft for some time and being commented on from relevant sources inclusive the transplantation center at Helsinki University Hospital. The health authorities are inspired by the former directives on blood and tissue and cells.

Norway: The official documents are produced and in a hearing phase.

Denmark: The EU Directive has been transposed to the law in February 2012. Now ministerial order is in process. Some financial issues have to be solved with the regions. Concerning data management a working group look on some practical issues inclusive degree of delegation to Scandiatransplant. NGR has sent a request to the Danish data protection agency to clarify if it is necessary to have some additional agreements because the Scandiatransplant database has a content of data from citizens from all five member states (Denmark, Sweden, Finland, Norway, Iceland). It is investigated if we need to have special agreements on data from the Health Authority in each country to secure that delegation of data management can be delegated to the Scandiatransplant database situated in Aarhus under Danish law and Danish data protection agency allowance.

Sweden: Also in steady process.

All countries expect to have fully implemented the law text and ministerial orders in the beginning of next year.

6b. Discussion on handling the alert system in each country.

There are problems with definitions of Severe Adverse Events (SAE) and Severe Adverse Reactions (SAR). Pål-Dag Line (PDL) has commented to Helsedirektoratet that in Norway as in the other countries, the health care system has an obligatory system to report such events ("utilsigtede hændelser" in Danish). What is specific for organ donation and transplantation itself? A longer hospital stay? no. What one needs is a short guideline of which has to be regarded as SAE and how to handle that at the transplant center, at the health authority and in relation to Scandiatransplant data registrations. Oslo will try to make such a prototype of a guideline. The art is to balance the activities of registrations of what is clearly regarded as SAEs (Transmission of Infectious disease, transmission of malignancy, major surgical incidents, and maybe a few others). There was a suggestion if it was possible to register a few major SAEs in the Scandiatransplant datasystem? First we need more clarifications and then we can discuss with the computer personnel if it is possible to add some extra fields for these few selected SAE recordings.

Rikshospitalet, Oslo is member of Scandiatransplant and therefore also co-owner of the Scandiatransplant datasystem. Therefore it should be possible to look at Scandiatransplant datasystem in Denmark as a part of the individual transplant centers' own activity, i.e. Rikshospitalet, Oslo. In the near future it is hoped that a prototype of a formular and a supplement can be worked out and be a part of an agreement with Scandiatransplant and each transplant center/each national health authority.

From Sweden, Tesi Aschan mentioned that inspection will be introduced in one way or another, it is not fully described how it will be integrated.

6c. Delegation of duties to "competent authorities" (Transplant centers, Health authority, Scandiatransplant office).

See remarks above.

6d. List of things to do as a consequence of content under issue 6c.

See remarks above.

7. Rapid alert systems (EU office).

During the summer 2012, EU office in Brussels has initiated an alert system for messages relevant for the transplant community. Each country has found a solution. In Denmark it is the transplant coordinator duty at Rigshospitalet, Copenhagen that has got the duty to receive and transmit messages to relevant persons/centers. The other countries (Sweden, Finland, Norway, Iceland) have similar systems centered in the transplant centers by those personnel on duty.

8. Any other business

News from Scandiatransplant: The information was given that Niels Grunnet, the medical director for 14 years, has decided to stop in this function per November 1, 2012. This is due to workload at the fulltime position as medical director for transfusion activity in the eastern part of region central Denmark at department of clinical immunology, Aarhus University Hospital, Denmark. Chief Physician, dr.med. Kaj Anker Jørgensen, department of nephrology, Aarhus University Hospital has been appointed to be the successor as medical director for Scandiatransplant in a half-time position which is an increase of the number of working hours per week affiliated to Scandiatransplant in the function of medical director. Today 8 persons are working at the office, Kaj Anker Jørgensen will begin his new function on November 1, 2012 with Niels Grunnet as consultant in the first two months. Niels Grunnet was thanked by the audience for his efforts and work in relation to the Nordic Transplant Committee in the dialogue between the National Health Authorities and the Scandiatransplant association.

Krister Höckerstedt reported on a serious event in Germany involving criminal activity of falsifying data to get own patients higher up on the waiting list in the Eurotransplant

cooperation, and the event has sent echos throughout the transplant and health care system in Germany, now being taken care of.

Krister Höckerstedt also informed that at a recent meeting in Brussels 13-14 Sept., it was stressed that the EU Cross Border directive of patient mobility is not covering organ transplantation and can therefore not affect the systems for organ transplantations within Europe. Organ Donation with organs intended for transplantation are covered by a specific Directive EU53/2010.

9. Next meeting September 2013 (Oslo/Stockholm?)

Planned to be September 24, 2013 in Oslo held at "Helsedirektoratet" (Directorate of Health). On September 23, 2013 there will be a meeting in the board of Scandiatransplant also in Oslo.

Writer of minutes: Niels Grunnet