

Oct. 6, 2017

MINUTES OF MEETING

Meeting No: 22nd meeting of the Nordic Transplant Committee

Time: Oct. 3, 2017 at 09:00-12:00

Venue: Scandic Park Hotel Helsinki, Finland

Participants:

Competent Authorities:

Norway: **No CA present**

Finland: **Tuija Ikonen**, Ministry of Social Affairs and Health

Pirkko Puranen, Finnish Medicines Agency Fimea

Sweden: **Helena Ström**, The National Board of Health and Welfare

Pia Oscarsson, Health and Social Care Inspectorate, Stockholm (IVO)

Denmark: **Maria Herlev Ahrenfeldt**, Danish Health Authority

Ole Boye Fjord Therkelsen, Danish Patient Safety Authority

Iceland: **Jórlaug Heimisdóttir**, Directorate of health

Estonia: **Ingrid Ots-Vaik**, Ministry of Social Affairs

Scandiatransplant:

CHAIRMAN: Bo-Göran Ericzon, Stockholm

SWEDEN: Lars Wennberg, Stockholm

FINLAND: Helena Isoniemi, Helsinki (replacement for Arno Nordin)

NORWAY: Moren Hagness, Oslo

ICELAND: Runolfur Palsson, Reykjavik

DENMARK: Finn Gustafsson, Copenhagen

ESTONIA: Virge Pall, Tartu

Director of Scandiatransplant:

DENMARK: Kaj Anker Jørgensen, Aarhus (KAJ)

1. **Welcome:** Pirkko Puranen from Finnish Medicines Agency Fimea bid everybody welcome for this meeting.
2. **Election of chairman of meeting and writer of minutes:** Bo-Göran Ericzon was elected chairman of the meeting and Kaj Anker Jørgensen was elected writer of the minutes with help from Pirkko Puranen, Finland.
3. **Approval of minutes from meeting No. 21, Sept. 20, 2016, Reykjavik, Iceland**
<http://www.scandiatransplant.org/members/ntc/MINUTESNordicTransplantCommitteemeeting2016Sept20Reykjavik.pdf>
Kaj scrolled through the minutes and these were approved.
4. **Additional issues for the agenda:** There were no additional issues.
5. **Tartu University Hospital in Estonia is now an associated member of Scandiatransplant:**

Virge Pall gave a power point presentation with an overview of transplantations in Estonia from the beginning. How many transplantations had been performed for every organ and how many grafts were still functioning. She showed the organization and the authorities involved and ended with a slide that showed what Tartu had gained from cooperation with Scandiatransplant and which hopes they had for the future for this cooperation.

6. **Transplantation/import/export activities in each country in 2016:**
<http://www.scandiatransplant.org/resources/AnnualScandiatransplantdatareport2016.pdf>
In the minutes in the last NTC meeting it was stated that the competent authorities would like an overview of the transplantation status and import and export activities of every country. KAJ told them that this has now been incorporated in Scandiatransplant's annual report which can be found on the Scandiatransplant homepage. The competent authorities have received a link to the homepage. He then gave a small presentation of a few selected data from the report as examples. The overall import and export from Scandiatransplant to other organ exchange organisations is very small. If there is imbalance between import and export from countries this is dealt with in full openness in the organ groups.
7. **Participation in EU funded projects (EDITH):** KAJ gave a short historic overview of the past ACCORD and EFRETOS projects and the relation to the EDITH work package 5 and 6. The board has discussed this matter and has concluded that Scandiatransplant does not want to be a partner in these projects. Scandiatransplant would rather use resource in making conditions better for our patients than put many resources into these projects, which we think would be of little help for the populations in the Scandiatransplant area. The participation in these projects is for countries so it is for the competent authorities to discuss this. The competent authorities will have a meeting just after the NTC meeting and they will discuss this and then give a feedback to Scandiatransplant of what they feel.
8. **Status of the Data Processor Agreements:** KAJ once more gave a very short overview of the background for these agreements. The status is that 7 out of the 11 hospitals now have signed agreements with Scandiatransplant: Oslo, Skåne, Stockholm and Uppsala are still missing and they will get a reminder. The NTC meeting concluded that it is very important to get these agreements in place. This also in relation to point 9.
9. **SAE/SAR reporting:** Lars Wennberg demonstrated the program created at Scandiatransplant as a tool for the hospitals to report the SAE/SAR to the competent authorities. It was emphasized that it was not Scandiatransplant reporting but the hospitals reporting to the competent authorities, and the owner of the data is the hospital not Scandia. We should in the report also have the possibility to report a SAE/SAR happening on an organ exported to a non-Scandiatransplant country and a note on what action has been taken on this. It should still be double-checked by the competent authorities that the report includes all information required by national legislation. CAs should also send to Scandia e-mail-addresses where reports could be sent (secured e-mails). Testing time long enough by using Scandiatransplant reporting tool in parallel with the existing reporting systems should be used to show that Scandiatransplant tool works adequately.
10. **What has happened in the last 12 months in each country: Competent authorities. Main transplantation and administrative issues:**
 - a. **Denmark:** Ole Boje Fjord Therkelsen said that no inspections had been done yet in Denmark but there will be inspections of transplantation centers in the last part of November. They have just had a meeting with the clinicians regarding these inspections. They are also discussing how and who is to inspect Scandiatransplant and KAJ said they were very welcome to come and inspect Scandiatransplant. Marie Arenfeldt from the Danish Health Authority told that the action plan for organ donation, organ care and care for relatives had been initiated earlier. There has been a status report which is on their website. The initiative had been implemented. They are now going to look at other departments than the ICU for the possibility of a donation. They have made a video about brain death/organ donation to tell the public that when a person is brain dead he is really dead. They are discussing how to visualize the Danish

donor registry. The Ethical council has discussed about presumed consent and had concluded that it should not be implemented in Denmark at this time. Anonymous donation can be done in Denmark without any legal problems, but has not been done. Sundhedsstyrelsen expects to be asked to give a recommendation regarding anonymous donations, but this has not happened yet.

b. Iceland: They have been given public information on donation and transplantation. They are asking for resources for practical matters. They also have made a video to raise public awareness. The legislation is from 1991 and they want it changed to include presumed consent, but because of the very frequent elections to parliament in Iceland this does not seem to be handled soon. They are working on a database according to the EU directive.

c. Estonia: Parliament is changing some details in the laws regarding transplantation and donation. They plan to make research on why some people do not consent with the donation and transplantation activity. They are also looking at how transplantation is financed. It has now by law been decided that Tartu is the only transplantation center in Estonia.

d. Sweden: Pia Oscarsson (IVO) said that there was no news after the last meeting, when all four transplantation centers already had been inspected. Report based on the inspections is available on IVO web page. Helena Strøm from Socialstyrelsen said they were waiting for decisions to be made following the last investigation. They are working on a national action plan inspired by Finland. They have 3 videos on their website.

e. Finland: Tuija Ikonen from Ministry of Social Affairs and Health told that the ministry had nominated an expert group. The central coordinator position in Helsinki with the responsibility to coordinate national donation activities has not been filled yet. There is work on legislation going on to allow also not closely related relatives to donate. This work was started but has been stopped because of the work load in the Ministry.

Pirkko Puranen, Fimea: They will make a second inspection of the transplantation center later on this year (first inspection was done in 2015). All five university hospitals and six other hospitals have been inspected since 2014. In the inspection they also ask how the national action plan has been implemented. to be nominated. **Norway:** There was no CA present from Oslo, but Morten Hagness from the board told that they had inspections in February.

11. Any other business: No issues.

12. Next meeting (Oct 2nd, 2018 Oslo/Tartu?): It was agreed that the next meeting would be held on October 2nd, 2018 in Tartu.

Kaj Jørgensen/ Pirkko Puranen