Oct. 4, 2016

MINUTES OF MEETING

Meeting No: 21st meeting of the Nordic Transplant Committee

Time: Sept. 20, 2016 at 12:00-16:00

Venue: Center Hotel Plaza, Reykjavik, Iceland

Participants:

Competent Authorities:

Norway: **Jorunn Svendsen,** Norwegian Directorate for Health
Finland: **Jaakko Yrjö-Koskinen,** Ministry of Social Affairs and Health
Pirkko Puranen, Finnish Medicines Agency Fimea
Sweden: **Mona Hansson**, Inspektionen för vård och omsorg (IVO)
Denmark: **Maria Herlev Ahrenfeldt,** Danish Health Authority
Anne Cathrine Bollerup, Danish Patient Safety Authority
Iceland: **Jórlaug Heimisdóttir**, Directorate of health

Scandiatransplant:
CHAIRMAN: Bo-Göran Ericzon, Stockholm
SWEDEN: Lars Wennberg, Stockholm
FINLAND: Arno Nordin, Helsinki
NORWAY: Pål-Dag Line, Oslo
ICELAND: Runolfur Palsson, Reykjavik
DENMARK: Finn Gustafsson, Copenhagen

Director of Scandiatransplant:
DENMARK: Kaj Anker Jørgensen, Aarhus (KAJ)

A G E N D A

1. Welcome:
Jórlaug Heimisdóttir from the Directorate of Health in Iceland welcomed everybody being the host of the meeting.

2. Election of chairman of the meeting and writer of the minutes:
Chairman of the board of Scandiatransplant Bo-Göran Ericzon was elected chairman of the meeting and Kaj Anker Jørgensen, Medical Director Scandiatransplant was elected writer of minutes. All participants then presented themselves.

3. Approval of minutes from meeting No. 20, 2015:
http://www.scandiatransplant.org/members/ntc/MinutesNordicTransplantCommitteeMeeting22.Sept.2015Copenhagen.PDF
In the minutes of the last NTC-meeting under point 8 it is stated from Norway that the SAE/AE reporting is in place. This is not completely correct, because there is not a separate reporting for these

events regarding transplantation and donation as is required from the EU directive. The reporting is through the Norwegian system for reporting all serious adverse events and reactions.
Otherwise no comments to the minutes from the last meeting.

4. Additional issues for the agenda from the participants:

There were no additional issues.

5. New Articles of the Association "Foreningen Scandiatransplant":

http://www.scandiatransplant.org/about-scandiatransplant/organisation/ArticlesofAssociationforForeningenScandiatransplant.pdf

KAJ gave a short overview of the organisation of Scandiatransplant. The articles of the association are from 1992 and do not reflect what Scandiatransplant is doing today, so there has been a big need for revising the articles. After two years of work, the articles have been revised and accepted by the council in May 2016. The major changes have been that the purposes of Scandiatransplant have been redefined, the groups in Scandiatransplant have been defined, the number of representatives has been changed, and the Scandiatransplant office has been defined. A possibility for associate membership has been put into the new articles. This is related to an application from Estonia to join Scandiatransplant. This was not possible in the old articles, but according to the new articles, Tartu hospital will be recommended by the board to the council meeting in May 2017 to become an associate member. Associate members work in Scandiatransplant like all the other members, but they do not have voting rights at board- and council meetings. The competent authorities agreed that if Tartu becomes an associate member of Scandiatransplant, a representative from the national authorities of Estonia and a representative from Tartu hospital should be invited to join the next NTC-meeting.

6. Status on work on Data Processor Agreements:

KAJ told the participants that Scandiatransplant has converted from the old text based system to the new YASWA-system. It is more user friendly, but has been very necessary due to security reasons. The program has been developed by the programmers of Scandiatransplant who have been working on it for the last seven years. He then showed a slide from last year demonstrating the legality and the problems with the legality of the data registration in the Central Region Denmark IT-system as it has been until now. Like last year he demonstrated a new model where each hospital is the data responsible authority for the data on their patients. This requires data processor agreements between each hospital and Scandiatransplant. So far such data processor agreements have been signed with Helsinki and with Aarhus, also a subprocessor agreement has been signed between Scandiatransplant and the IT-department of Central Region Denmark. The agreement with Odense is ready for signatures and a lawyer at Rigshospitalet in Copenhagen is working on a data processor agreement with Copenhagen. It was discussed how to proceed in Sweden, Norway and Iceland. For Sweden it was decided, that although it was each hospital who has to make the agreement and sign, we should first contact lawyers at SKL to try to formulate agreements with all Swedish hospitals which were the same. We should let this go through Tesi Aschan. Bo-Göran Ericzon and KAJ will take initiative in this matter. In Norway Pal-Dag Line will take an initiative to Rikshospitalet in Oslo. Runolfur Palsson will initiate the process in Iceland.

7. SAE/AE reporting:

The suggestion from Lars Wennberg was sent to the competent authorities before the meeting. They were all in favour of the suggestion which should be for SAE/SAR. Further work on defining how the reports should be will be done with Lars Wennberg as key person. Primarily he will collect information from all the competent authorities, and the board will work on this suggestion. When this is clear, the suggestion will be taken to the office in Aarhus for the programmers to start doing the programming process. This will take some time. The suggestion was that SAE/SAR should be reported into an IT-system in Scandiatransplant which automatically transfers this to the involved competent authorities in the form they require. At the same time SAE/SARs that require an immediate alert, could be sent out to the involved parties, probably by SMS and e-mail in a way like we do the organ offer form. Both the board and the competent authorities would like some kind of yearly report on these events and reactions. The aim is that the new system is demonstrated at the next meeting of Scandiatransplant with the Competent Authorities in 2017.

8. What has happened in the last 12 months in each country: Competent authority

- **Main transplantation and administrative issues including the EU-Directives.**

a. Denmark:

It has been a turbulent year due to organisation changes, Denmark is implementing the national action plan mentioned last year, and progress will be assessed later this year. They are focusing on the prehospital phase and other departments than the ICUs. There is good cooperation and good initiatives taken from the Danish Center for Organ Donation. The Danish Health Authority is mainly responsible for information to the general population. Only 1/5 of the population is registered in the organ donor registry, so they will focus on information on brain death and improve their website.

b. Norway:

Persons responsible for organ donation have been identified in all hospitals. There is a new transplantation law in force from the beginning of the year. The new law does not dictate, that there has to be made an angiography, but that this can be replaced by similar investigations. You can now treat a "hopeless" patient with the goal of being a donor. This is important for DCD for which they have a program in Norway. Much work has been done to deal with interpretation of the new regulations and how to accommodate and manage that into practice. There has been established a national professional network consisting of surgeons, coordinators, donor responsible doctors and nurses from hospitals in all regions, organisations, and people working with population based information. In their last meeting they invited Jaakko Yrjö-Koskinen from Finland to present the Finnish action plan which they find very inspiring. They had decided not to make new guidelines for donor hospitals, but rather to revise and update established protocols well in use in all donor clinics. In addition, the Norwegian board of health has started up supervision activities toward the procurement hospitals, and they plan to make a summary of this work in the near future.

c. Sweden (IVO has announced a presentation):

Mona Hansson gave a presentation of the inspection of the transplantation activities in Sweden. They found that the communication and collaboration was very good. There was a need for highly specialized personnel and the teams were small, so the system is quite vulnerable, the system was dependent on the ICU being able to identify potential donors, and there was also in some places a lack of resources. They found that transplant centers were not familiar with Scandiatransplant IT-security, and that audits with contractors like Scandiatransplant should be done. There was some insecurity about what should be reported to IVO. On the whole they found that the organ donation and transplant systems were functioning well in Sweden. KAJ added that Scandiatrans-plant had been inspected by the transplant center in Malmø and showed the result in a document produced by Ragnar Källén.

d. Finland:

An advisory board was set up in April to steer, coordinate and monitor organ donation activities. A national donor coordinator has not been appointed yet due to difficulties in agreeing where to establish the position. The Ministry of Social Affairs and Health is exploring the possibility to revise the legislation to allow other persons to act as live donors in addition to close relatives and persons living in the same household. Inspections of donor hospitals have been initiated and the conclusions were similar to the ones that were drawn in Sweden. Jaakko Yrjö-Koskinen also reported briefly on the Nordic meeting that was organised in the vicinity of Helsinki in October. The meeting brought together for the first time representatives of all stakeholders to share country experiences and best practices. The participants to that meeting shared the view that such a meeting should be a recurring event.

e. Iceland:

In Iceland a bill on a new organ donation legislation featuring presumed consent was discussed in Parliament in 2014, but it was not passed, and in 2015 the Parliament refused to discuss the bill. A working group on organ donation was previously established to develop an action plan, but it was not implemented due to lack of resources. At the moment Iceland is in the process of implementing the EU directive. They are creating an official database for follow-up of the

transplant recipients. Iceland has been cooperating with Sahlgrenska in Gothenburg since 2010, and they are now evaluating this cooperation.

9. Any other business:

None, but after the meeting the competent authorities expressed a wish to see figures on each country's transplantation activities, organ export/import between Scandiatransplant countries, and organ export/import out of Scandiatransplant.

10. Next meeting

It was decided that the next meeting should be on October 3rd, 2017 in Helsinki.

Kaj Jørgensen