

Oct. 5, 2018

MINUTES OF MEETING

Meeting No: 23rd meeting of the Nordic Transplant Committee
Time: Oct. 2, 2018 at 09:00-12:00
Venue: V Spa Hotel & Conference Center, Tartu, Estonia

Participants:

Competent Authorities:

Norway: **Tone Blørstad, Gunnar Misvær**, Directorate of Health
Finland: **Tuija Ikonen**, Ministry of Social Affairs and Health
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: **Siim Suutre**, State Agency of Medicines
Malle Avarsoo, Estonian Health Insurance Fund

Scandiatransplant board:

CHAIRMAN: Bo-Göran Ericzon, Stockholm
SWEDEN: Tomas Lorant, Uppsala
FINLAND: Arno Nordin
NORWAY: Morten Hagness, Oslo
ICELAND: Runolfur Palsson, Reykjavik
DENMARK: Finn Gustafsson, Copenhagen

Invited associate member:

ESTONIA: Virge Pall, Tartu

Invited earlier board member:

SWEDEN: Lars Wennberg, Stockholm

Director of Scandiatransplant:

DENMARK: Kaj Anker Jørgensen, Aarhus (KAJ)

Agenda

- 1. Welcome:**
Virge Pall bid welcome to Tartu. Introduction of participants.
- 2. Election of chairman of meeting and writer of minutes:**

Bo-Göran Ericzon was elected chairman of the meeting and Kaj Anker Jørgensen writer of minutes with the help from Siim Suutre.

- 3. Approval of minutes from meeting No. 22, Oct. 3rd, 2017, Helsinki, Finland:**
<http://www.scandiatransplant.org/members/ntc/MINUTESNordicTransplantCommitteemeeting2017Oct3Helsinki.pdf>

Kaj scrolled through the minutes and these were approved.

- 4. Additional issues for the agenda:**

Pia Oscarsson, Sweden suggested a discussion of what the board expected from the CAs at these meetings.

- 5. Scandiatransplant 50 year jubilee, May 9th, 2019:**

Kaj told that Scandiatransplant will celebrate its 50 year jubilee on Thursday May 9th 2019 in Aarhus. The jubilee will take place from 14:00-16:00 at Aarhus city hall. The main target is the public and the media and not health workers within the organisation, they will celebrate this at the STS congress next year. There will focus on patient case stories, and we have hired a company to make videos. We have invited Crown princess Mary of Denmark who is protector of the Danish Heart and Kidney patient organisations and Prince Daniel of Sweden who has undergone a renal transplant himself. There will in the evening be a dinner at Aros Museum in Aarhus.

- 6. Status on the Data Processor Agreements:**

We now have signed agreements from nine of the eleven member hospitals (data owners). We are still missing Stockholm and Oslo.

- 7. GDPR:**

Kaj told that the office gets questions regarding GDPR. We are pressing hard to get all the processor agreements. We have made standardised reports so people can report breaches. One person from the office will take a course and be authorized in GDPR this year, mainly to help us be able to answer questions from our users. The question of consent is the responsibility of the data controllers, namely the hospitals.

There was then a lengthy discussion about this item and it was clear that there are many grey zones and that many authority hospitals and universities have still not been able to produce clear guidelines on these matters. It was said that in Finland, they have proposed a law to help in these matters.

- 8. SAE/SAR reporting / Finland does not want all reports?/ Wishes for Annual Report?:**

Kaj told that the system has been working since new year and by October 1st there had been eight SAE reports, three from Copenhagen, two from Gothenburg, two from Oslo and one from Uppsala. Four of the reports were on possible transmission of cancer from donor to recipient, one was on positive culture for MRSA in a lung donor after recipients had been transplanted but cultures from all recipients were negative, two recipients died shortly after transplantation of acute myocardial infarction, and one kidney recipient with a BMI of 55 died shortly after transplantation of an influenza pneumonia. Kaj asked if there were special wishes for the annual report, but the Competent Authorities primarily wanted the report to have the facts that are to be reported and can be found in the directive. They want a report where you can see what happens in your country but also in the other countries. At the Scandiatransplant council meeting it was stated that Finland does not want to see reports which do not involve the Finnish centers, and Kaj therefore raised a question, but it was concluded that the Finnish CA would still receive reports from all centers as agreed upon last year. There then was a long discussion on SAEs and SARs. When creating the program these were thought as one unity, and actually doctors do not know the difference between SAE and

SAR, but according to the definition there is a difference and the CAs have to report specifically on SAEs and SARs to the EU Commission. An SAE is an event that is unexpected and could lead to some kind of harm. The SAR is the reaction when there actually were consequences of an event. It was decided to make the program so you can tick off if it is an event, a reaction or both. It proved that the IVO in Sweden had not received any of these reports. Kaj should find out what e-mail address we are sending these to in Sweden and send this to Pia Oscarsson and clarify what has happened. This led to some uncertainty of the system, and there was a big need to ensure a control that all CAs got the reports. The conclusion was that Scandiatransplant should send out a test every third month, and this test should also state the number of reports that had been sent out the last three months. Then the CAs can see if they are missing some. It was also agreed that CAs would reply to the test reports sent out by Scandiatransplant to confirm that they have received them. Some countries had received the test reports that were sent out when the system started and also all the reports.

9. What has happened in the last 12 months in each country: Competent authorities. Main transplantation and administrative issues:

- DENMARK:

Maria Herlev Ahrenfeldt told that the Danish Health Authority has focus on information about organ donation to the public as well as initiatives in the health care sector in regards to organ donation and transplantation. They are currently working on designing a new brochure about organ donation and in collaboration with the Danish Center for Organdonation planning a campaign by the end of the year to put more focus on the importance of making a choice about organ donation. Another focus is *Donation after Circulatory Death* (DCD), where the Danish Center for Organdonation has made a recommendation to supplement existing practice using organs after brain death with DCD in order to increase the number of transplantations from deceased. At the moment it is not yet decided how and when new procedures for DCD are launched. In regard to living donation they have also been working on designing a new frame work for anonymous kidney donation from living donors. Even though there are no obstacles in legislation today for doing this the practice is that a donor has to be a relative or an acquaintance of the kidney patient. There is a working group working on principles for how to support anonymous kidney donation, and they expect it to be a possibility from 2019.

Ole Boye Fjord Therkelsen from Danish Patient Safety Authority told that the three organ transplant hospitals in Denmark had been inspected in 2018 and they found very engaged people working in this sector and they found everything in good order. They did see that many SOPs had been updated recently.

- ESTONIA:

Siim Suutre told that in Estonia they have a transplantation council which has meetings three times a year. It consists of authorities, clinicians and Estonian Health Insurance Fund. State Agency of Medicines inspected Estonia's only transplantation hospital (Tartu University Hospital), who is also responsible for organ procurement and handling, back in 2014, but will now make a new inspection after Tartu University Hospital has become a member of Scandiatransplant.

- SWEDEN:

Pia Oscarsson told that they were waiting for a new construction in Socialstyrelsen who were forming a donation center and working on indicators of what the CA should focus on

during inspections. They are part of the EU vigilance program. CAs took part in a meeting on a global exchange in Italy in January.

Bo-Göran told that ScandiTransplant had signed support to the document by the European Transplant Communities, that we do not want to take part in this global exchange program primarily suggested by the Americans for ethical reasons.

Pia Oscarsson also told that patients have now to be included somehow when they make inspections.

Helene Ström from Socialstyrelsen told that they were creating a national donor center in Sweden and tissues and cells would be included in this. The 14th of March 2019 there will be a big event financed by an EU project on organ donation. Socialstyrelsen is in favor of public promotion of organ donation.

- ICELAND:

Jórlaug Heimisdóttir told that legislation has been passed so by January 1st 2019, Iceland will have presumed consent. They are now planning how this is to be implemented and how to make a registry where you can opt in and opt out. They are still waiting to get their database up and running.

- NORWAY:

Gunnar Misvær told that there is now a legal and ethical evaluation of their DCD program. They expect results of these investigations (Health Technology Assessment) in spring. The activity in their DCD program has therefore been put on hold and is waiting for the results of these investigations. They have done eight transplantations with DCD donors and all the recipients are doing well. They are making an information campaign on donation. It is primarily directed to health personnel, but then they are also making a core journal (kerne journal) where you can register if you want to be a donor. There are also discussions going on concerning a CT and cerebral angiography. In Norway some hospitals still use normal x-ray cerebral angiography and some are using CT angiography – Norwegian law requires these imaging analyses to be included in donor identification protocols.

- FINLAND:

Tuija Ikkonen told us that the parliament was working on the legislation for living donation so it would be possible to use anonymous living donors. The national coordinator is now in place in Helsinki. The action plan for organ donation will finish this year. There is some discussion how the work of the national council on organ donation will continue.

Bo-Göran stated that there should be inspection of donors' hospitals also.

Finn Gustafsson told that ESOT will be held in Copenhagen in the autumn of 2019. This is a big meeting with about 4000 participants.

10. Any other business:

Due to time the discussion of the expectations the board had to the CAs at these meetings was postponed until next year.

11. Next meeting (Oslo ?, October 3rd, 2019 ?):

It was decided that the next meeting should be October 3rd, 2019, in Oslo.