

8. Oct. 2019

MINUTES OF MEETING

Meeting No: 24th meeting of the Nordic Transplant Committee
Time: Oct. 3, 2019 at 12:00-15:30
Venue: Helsedirektoratet, Oslo, Norway

Participants:

National Health Authority representatives:

Norway: Jorunn Svendsen, Tone Blørstad, Eva Elander Solli, Norwegian Directorate for Health
Finland: Arno Nordin
Sweden: 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: Jóhann Jónsson
Estonia: Siim Suutre, State Agency of Medicines

Scandiatransplant board:

CHAIRMAN: Bo-Göran Ericzon, Stockholm
SWEDEN: Johan Nilsson, Lund
FINLAND: Arno Nordin
NORWAY: Morten Hagness, Oslo
ICELAND: Jóhann Jónsson, Reykjavik
DENMARK: Allan Rasmussen, Copenhagen

Invited associate member:

ESTONIA: Virge Pall, Tartu

Director of Scandiatransplant:

DENMARK: Kaj Anker Jørgensen, Aarhus (KAJ)

Agenda NTC meeting Oct. 3rd, 2019, Oslo, Norway.

1. Welcome:

Jorunn Svendsen bid everybody welcome to Oslo and told us the directorate had worked in this new building for one year.

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

Bo-Göran Ericzon was elected chairman and Kaj Anker Jørgensen was elected writer of minutes with the help of Jorunn Svendsen.

3. Approval of minutes from meeting No. 23, Oct. 2nd, 2018, Tartu, Estonia. ([link](#)):

The minutes were approved.

4. Additional issues for the agenda:

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

- a. Competent authorities: Main transplantation and administrative issues.
- b. Board members: supplementary information.

NORWAY:

Eva Elander Solli/Jorunn Svendsen told about the campaign at all donor hospitals last year. The aim has been to increase organ donation and consequently the number of organ donors in the hospitals. The campaign had got a lot of public attention. It is difficult to estimate the long term effect. It was the 4 regional health authorities who had the responsibility for the campaign and it will continue in the South-Eastern Region. She told about the good results in the DCD project, but it had stopped to be evaluated. A high level group of experts will consider legal, medical and ethical aspects. It is expected to be made public in November.

Tone Blørstad: There had been inspections on all 26 donor hospitals. Inspection of the transplant centers is done every year. They found out that the follow up management at the donor hospital is not perfect and there is training going on.

SWEDEN:

Pia Oscarsson: The IVO has not yet made inspections of donation centers, but a survey of the donation hospitals is ongoing and the result will form the basis for decisions on further supervision. How the supervision will be performed is not yet clear. She also said that Socialstyrelsen is working hard on the DCD project and informing new donation center.

ESTONIA:

Siim Suutre: Explained how these things are done in Estonia. Inspection of donor hospitals lies within another authority. They have inspected Tartu and found everything working well inclusive Yaswa. There is a national transplantation council where they have discussed DCD. He also said that the SAE/SAR reporting is working well.

DENMARK:

Maria Herlev Ahrenfeldt: The main issues in Denmark is DCD as well as communication to the public about organ donation. The background for the discussion of DCD is a report from the Danish Center for Organ Donation where a working group recommended that DCD should be a supplement to donation after brain death. A broad political agreement to strengthen the transplant area by allowing DCD has been reached and there are no legal restrictions to introducing DCD, but there is a need to establish national procedures before implementing. The Danish Health Authority has set up a working group for this. DCD is expected to be implemented in 2020 or 2021.

There has been focus on a new communication strategy for organ donation. A new leaflet has been designed and will sent to 430.000 individual digitally by their e-boks. The age where you can register as a potential donor has been decreased to 15 years.

Ole Boye Fjord Therkelsen: Told about the inspection of the tx-centers, they will probably make inspections every third to fourth year. They would like to try and see if it is possible to make regulations about this matter, the same in the different Scandiatransplant countries, but this will be difficult.

ICELAND:

Jóhann Jónsson on behalf of Jólauug Heimisdottir. They have passed a new law which is an opt-out system from January 1st, 2019. There has been much training. There is a good system to opt-out if you want to do this. They haven't seen any impact on donation rate yet. They are starting to address DCD.

FINLAND:

Arno Nordin on behalf of Tuija Ikonen. There have been changes in the law so that now they can perform living donations even if the donor is not related to the recipient. This means they can participate in the STEP and other programmes. They have had a national donor coordinator for two years who has gone to all the donors' hospitals, taught them, and at the same time the minister has organized an official campaign and this has been a big success since donor rates are really increasing in Finland. There is a committee looking at DCD.

6. Status on the Data Processor Agreements:

Kaj told them that we are now only missing Oslo and we really hope to get this problem solved soon.

7. Council of Europe Convention against Trafficking in Human Organs (CTS 216). EDQM document. Status for ratification in the different Scandiatransplant countries:

Only Norway has ratified this. There were minor suggestions for why it has not been ratified in other countries, but there was no clear conclusion. One of the reasons is that it has to be looked at within the criminal laws which may need a little change.

8. ONT: Newsletter Transplant. Who receives requests for the data?:

The competent authorities do not think that they get these requests. Kaj just informed them that if they get them or hear of somebody who gets them, it would be good to send the request further to the Scandiatransplant office so that we don't always have to get all these data within a very small time frame.

9. SAE/SAR reporting:

- a. Status 2019.
- b. Is it working OK?
- c. Do you want changes?
- d. The annual report.

Kaj gave a short overview of the reported SAE/SAR in 2019. He asked if it was working generally well and if the competent authorities were satisfied with this. This was the case. There is a problem that doctors report all these events at SAE although some of them are SARs. Since they have been reported as such, we should not change them in our database. Kaj told them that the intention in making the program was to make an initial report. If the competent authorities think that there should be follow-up, it is their responsibility to contact the reporting center or doctor. The competent authorities were also satisfied with the annual report I made last year and didn't have suggestion for changes.

10. Any other business:

There was a request to tell about the STEP program, and Kaj told them about the STEP program and the status we have right now. The programming in Yaswa is in place and we are waiting for the clinicians to take the final decisions for the Scandiatransplant STEP program to come into effect. Sweden has made some of these transplantations. There is a clinical group handling the practical aspects. This group has Per Lindnér from Göteborg as chairman.

The organ perfusing machines, which are now being more used in organ transplantation actually fall under the medical device directive. Ole Boye Fjord Therkelsen will try and look deeper into this matter by contacting the commission in Bruxelles.

11. Next meeting (Stockholm, October 1st, 2020 ?):

Will be held on October 6th, 2020 in Stockholm.