

1st Oct. 2021

MINUTES OF MEETING

Meeting No: 26th - Hybrid meeting of the Nordic Transplant Committee

Time: Sept. 28, 2021 at 13:00-16:00

Participants:

National Health Authority representatives:

Norway: ONLINE - **Jorunn Svendsen**, Norwegian Directorate for Health
ONLINE - **Øystein Flesland**, Norwegian Directorate for Health
ONLINE - **Eva Erlander Solli**, Norwegian Directorate for Health
Finland: ONLINE - **Sinni Tervo**, Ministry of Social Affairs and Health
Sweden: PRESENT - **Linda Savolainen**, The National Board of Health and Welfare
PRESENT - **Tesi Aschan**, Legal adviser for the National Board of Health and Welfare
PRESENT - **Pia Oscarsson**, Health and Social Care Inspectorate, Stockholm (IVO)
Denmark: ONLINE - **Maria Herlev Ahrenfeldt**, Danish Health Authority
ONLINE - **Marie-Louise Kirkegaard Mikkelsen**, Danish Health Authority
ONLINE - **Camilla Krogh**, Danish Health Authority
PRESENT - **Ole Boye Fjord Therkelsen**, Danish Patient Safety Authority
ONLINE - **Helle Haubro Andersen**, Danish Center for Organ Donation
Iceland: ONLINE - **Thorgunnur Hjaltadottir**, Directorate of health
Estonia: ONLINE - **Heli Paluste**, Ministry of Social Affairs
ONLINE - **Siim Suutre**, State Agency of Medicines

The board of Scandiatransplant:

PRESENT - Bo-Göran Ericzon, Stockholm
ONLINE - Arno Nordin, Helsinki
ONLINE - Johan Nilsson, Lund
PRESENT - Morten Hagness, Oslo
PRESENT - Allan Rasmussen, Copenhagen
ONLINE - Jóhann Jónsson, Reykjavik
ONLINE - Virge Pall, Tartu, Estonia

Medical Director of Scandiatransplant:

PRESENT - Kaj Jørgensen

Minutes of Nordic Transplant Committee meeting 28.09.2021 at 13.00-16.00

Hybrid meeting at Huddinge Hospital, F82
Hälsövägen 13, 141 57 Huddinge, Sweden

AGENDA:

1. Welcome - presentation of participants:

Linda Savolainen bid everybody welcome to this hybrid meeting of the Nordic Transplant Committee.

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

Linda Savolainen was elected as leader of meeting, and Kaj Jørgensen as writer of minutes

3. Minutes of last meeting ([link](#)):

Kaj went through the minutes of the last meeting and the minutes were accepted.

4. Issues for “any other business”:

No issues.

**5. Transplantation of refugees without a permanent permission to stay in the country
Linda Savolainen (Socialstyrelsen S):**

It had been decided at the last meeting that we would bring this point up at this meeting, and Linda Savolainen started this discussion by saying that there are no written, clear guidelines on how to proceed in these situations. Since we exchange kidneys within Scandiatransplant it would be good if the policies in this area do not differ too much between our countries. The discussion revealed that it will probably be very difficult to get exact, clear guidelines on this matter. Often it will be up to the doctors performing the transplantation to take the final decision. The opinion of ethical committees and immigration authorities may sometimes be opposite. In some countries the responsibility for the decision will be in the regions and not even national. It is important that people recognize that the organ transplantation is just a part of the package. The follow-up after transplantation with medical treatment and evaluations and investigation is equally important. If you transplant an organ and there is no possibility for lifetime follow-up, the risk for the organ and the patient is very large. So in principle you cannot perform an organ transplantation if the patient will not be able to get the correct follow-up. There seems to be some consensus that transplanting lifesaving organs in acute situations must always be done although this may have to be followed by the patient necessarily having to stay in your country if they cannot get the correct follow-up in the country they came from. When talking about a chronic disease, it is a more grey area and in the most cases for kidneys, people can be on dialysis until it can be clarified if they can get a permanent stay in the country. The Swedish society of transplantation has published an article with ten principles to help the transplant community in this situation. This article was shown at the meeting and discussed. Tesi Aschan told them that there will soon come a publication looking at the differences in the EU countries on this matter.

Morten Hagness thought that in Norway they were a little bit more liberal than in the other Scandiatransplant countries.

The conclusion was that there are no complete, clear guidelines from the authorities on these matters, and they will often have to be treated case by case.

6. What has happened in each country: CA supplemented by Board member:

- Sweden:

Linda Savolainen and Tesi Aschan:

Information about ongoing projects at the National Board of Health and Welfare.

Proposition 2020/21:48 Organ donation

Concerns medical intervention before death, the proposal was withdrawn due to questions about intubation. A new consultation document was recently received, new proposition will be presented in early 2022

Promotion of paediatric organ donation, a guidance with recommendations will be published at end of 2021

Revision of the Regulation of criteria for death SOSFS 2005:10 . The document will be sent out for consultancy soon

Government assignment-national registry for blood donors and plan for increasing blood donations in crisis A report will be published in march 2022

Revision of EU-directives for blood, tissues and cells

A proposal for new EU-directives is planned for the end of 2021

Pia Oscarsson from Swedish Health and Social Care Inspectorate (IVO) informed that the transplant/donation establishments in Sweden will not be inspected by IVO within the framework of frequency supervision (every second year as blood and tissue establishments) at the moment. The reason for this is that in the Organ Directive 2010/53/EU it is only stated that inspections must take place regularly, but not how often. IVO has an overall supervisory responsibility for all health care in Sweden and can of course inspect the transplant/donation establishments based on the Patient Safety Act if required.

- **Denmark:**

Ole Terkelsen: They have not made any ordinary routine inspections, they have only made inspections where it has been necessary e.g. in connection with commissioning of new facilities/rooms.

Maria Ahrenfeldt: Told us that the DCD working group was still working, but she hopes that DCD can be implemented in the four big University Hospitals Denmark in 2022. The plan is also to make an information campaign directed mostly to inform and debate DCD in the public. They have been working on a report on the differences in waiting time for kidney transplantation in different regions in Denmark. This difference is due to a different donor rate in different regions in Denmark and they are focusing on this. Kaj commented that the region in Denmark where the donor rate had been low previously had had a high donor rate for the first half of this year, but it is too early to say if this focus has helped.

- **Finland:**

Sinni Tervo: They will start audit of transplantation centers. All donor hospitals have been audited, and Arno Nordin thinks this happens about every third year.

Arno Nordin: He feels that the donor numbers are not as high as they could be. It seems like the donor numbers may have gone down after the Covid although they did not go much down during the Covid. The living donor program is expanding, and they will do many this year. They have started a pilot study on DCD, and after the laws have been changed, they can now participate in the STEP program and use altruistic donors.

- **Iceland:**

Thorgunnur Hjaltadottir: The topic was new for her and they feel that the pandemic may have decreased the donor rate. In Iceland now only the refusal to donation is

registered. She thought that the number of transplantations has not gone down due to the cooperation they have with Gothenburg. Jóhann Jónsson commented that deceased donor transplantation had gone up, the number of living donors had gone down, so the total number was about the same.

- **Norway:**

Jorunn Svendsen:

The cDCD project was paused during the method review and the regional health authorities ordered a compilation of the many consultation inputs to the method report by the NIPH Norwegian Institute of Public Health.

This year in August, The Decision Forum for new methods decided that the method may be used. Conclusions from the decisions are:

1. Organ donation using normothermic regional perfusion in patients with severe brain damage and who die of cardiac and respiratory arrest when life-prolonging treatment is discontinued, referred to as "controlled donation after circulatory death (cDCD)" may be used as a method as described in procedures for Oslo University Hospital (the Decision Forum for New Methods' meeting on 30.08.2021).
2. The procedures shall ensure that healthcare professionals can use the method according to a standard with the broadest possible professional foundation, and where the criteria for "Death after permanent cardiac and respiratory arrest" are clearly described.
3. The National Organ Donation Service at Oslo University hospital will be responsible for coordinating with the donor hospitals to ensure practice according to the procedures.
4. An evaluation of the use of cDCD shall be carried out, based on register data and experience with the method two years after implementation. An interregional director has the responsibility for the evaluation and the evaluation report will be presented to the Decision Forum for new methods.

Morten Hagness: Commented that through the last years, where this evaluation had been going on, they had lost 20 donors per year.

- **Estonia:**

Siim Suutre: They were a little behind on inspections in organ transplantation, legally this is stated that they should take place every second year, but this was due to the COVID-19. The National Institute of Health started publishing detailed statistics on procurement and handling of cells and tissues. It was decided that statistics about organ procurement and handling will not be published in such way. Estonia's national guidelines about donor selection during the COVID-19 pandemic are mostly based on the recommendations of ECDC, but also professional societies and Scandiatransplant.

Virge Pall: Last year they had 25 donors per million population, this has gone down this year, she expects it will be significantly lower this year, and this is due to overloaded intensive care units due to Covid. The airport situation is a little better than last year.

Ole Terkelsen, Denmark, drew attention to so called "deliverables" for the upcoming period for the European Committee on Organ Transplantation (CD-P-TO), amongst others a: "Draft legal instrument on the establishment and maintenance og harmonised transplant registers and international data sharing". CD-P-TO is a

committee under the European Directorate for the Quality of Medicines and HealthCare (EDQM) – which is a part of the Council of Europe. EDQM is often collaborating with the European Commission under the EU to prepare guidelines and legislation. It may be of the interest for ScandiTransplant to follow the development of such deliverables.

7. Any Other Business:

No issues.

8. Next meeting (Aug 31st, 2022, Reykjavik, Iceland in connection with STS congress?)

It was decided to have the next NTC meeting on August 31st 2022 in Reykjavik, Iceland in the morning. This in connection with the STS Congress that would start in the evening.