



Minutes of meeting

Meeting No: 29th meeting of the Nordic Transplant Committee

Time: Sept. 26th, 2024 at 12:00-14:00

Venue: Swisshotel, Tallinn, Estonia

Present:

HEALTH AUTHORITIES:

Iceland:

Pórgunnur Hjaltadóttir, Directorate of Health

Norway:

Tone Andersen, Norwegian Board of Health Supervision

Ragnhild Marie Sørensen, Norwegian Directorate for Health

Sigrid Beitland - Norwegian Directorate of Health

Ranjan Chrisanthar, Norwegian Directorate for Health

Denmark:

Marie-Louise Kirkegaard Zobbe - Danish Health Authority

Kasper de Laurent Stenalt, The Danish Patient Safety Authority

Estonia:

Siim Suutre, Republic of Estonia Agency of Medicines

MEDICAL DIRECTOR:

Kaj Jørgensen Medical Director of Scandiatransplant

BOARD MEMBERS OF SCANDIATRANSPLANT:

Allan Rasmussen, Copenhagen

Marko Lempinen, Helsinki

Johan Nilsson, Lund

Are Martin Holm, Oslo

Jóhann Jónsson, Reykjavik

Virge Pall, Tartu, Estonia

1. Welcome.

Siim Suutre welcomed all attendees to Tallinn, followed by a brief round of introductions.

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

Allan Rasmussen was elected to chair the meeting, while Siim Suutre was appointed as the writer of minutes.

3. Ask for issues for any other business.

No additional items were proposed for inclusion under Any Other Business.

4. Minutes of last meeting.

The minutes from the previous meeting, held on October 4, 2023, in Copenhagen, were approved as presented.

5. SAE/SAR.

Kaj Jørgensen delivered a presentation on the Scandiatransplant IT platform's system for reporting Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR), which was developed to comply with EU regulations. It was emphasized that while the Scandiatransplant platform is the reporting tool, the content responsibility lies with the hospitals and individuals initiating the report through the YASWA system. Additionally, it was clarified that further communication beyond the initial report must be conducted via national reporting systems, as the Scandiatransplant system does not support subsequent exchanges between hospitals or their respective competent authorities.

The Norwegian Directorate of Health highlighted that, under Norwegian law, initial reports must be submitted directly to the Norwegian competent authority, with more detailed information than currently required by the Scandiatransplant platform. As Norway's definitions for SAE and SAR are broader than those in the EU Directive, the national reporting system may be more appropriate for Norwegian hospitals. Hospitals may find themselves submitting reports via both the Scandiatransplant IT platform and the Norwegian system. The group discussed whether the dual reporting process, given the relatively low number of cases per year, would pose a significant burden before considering modifications to the Scandiatransplant platform to accommodate varying national requirements. This issue will be revisited at next year's meeting. Are Martin Holm asked for the purpose of this registry. The Hospital deals with unintended preventable events and the Scandiatransplant system is also for the benefits of the patients working 24/7, while this new system the authorities would not benefit any patient when needed. He also asked for the different authorities to communicate referring to the unsolved problems of giving Scandiatransplant access to the know if a person is dead or alive – an issue that has been known to raise some questions about data protection.

The

The Danish Patient Safety Authority raised concerns about potential underreporting of SAE and SAR due to gaps in the analysis of the full process, from donation to transplantation. This may stem from insufficient awareness of which incidents should be reported. It was acknowledged that different countries might have varied definitions or interpretations of SAE and SAR, as outlined in the Organ Directive. Furthermore, some cases may go unreported due to data protection concerns. There was consensus that any preventable issues should be reported. It was suggested that contact information of the chairs of organ-specific working groups, who discuss reportable case. Kaj Anker Jørgensen will give information to the Danish Patient Safety Authority to facilitate more direct communication.

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

Estonia: Siim Suutre

Regulation (EU) 2024/1938 of the European Parliament and the Council, concerning standards of quality and safety for substances of human origin (SoHO) intended for human application, was published in EUR-Lex on June 13, 2024, and will take effect on August 7, 2027. The Estonian Agency of Medicines was consulted on the translation of the regulation. Although this regulation does not apply to organs for transplantation, there is still a reference to the Tissues and Cells Directive 2004/23/EC in the Organs Directive 2010/53/EU. It remains to be seen how this reference will be handled when it becomes outdated.

In May 2024, the European Commission distributed the survey on the state of organ vigilance and a pilot for Organ SAE/SAR data collection (covering 2023 data). Estonia reported no changes in the state of organ vigilance and no SAE/SAR related to organ procurement or handling.

West Nile virus was detected in blood donors in France, and ANSM disseminated recommendations for managing both donors and recipients, including organ donors. This document was shared with local establishments licensed for the procurement and handling of cells, tissues, and organs. A risk-based approach is permissible.

Technical updates were made to the national registry of licenses for the procurement and handling of cells, tissues, and organs. The registry now publicly displays the individuals responsible for procurement and the competent persons overseeing handling activities.

A joint meeting of the Competent Authorities on Blood and Blood Components, Tissues, Cells, and Organs took place on March 6, 2024, as a virtual event. The meeting primarily focused on the new SoHO regulation. During the meeting, participants also presented the recommendations from the Global Convergence in Transplantation Summit (Santander Statement) to governments. These recommendations included guidelines on patient care, transparency, and oversight, with the aim of preventing human organs, tissues, and cells from becoming commercialized.

One donor hospital was inspected, with no critical or major non-compliances found.

In May 2026, Tartu University Hospital will host the Congress of the Scandinavian Transplantation Society.

Denmark: Marie-Louise Kirkegaard Zobbe

DCD was after several delays started in the fall of 2023. It is currently implemented in three of the university hospitals. Overall, it is going very well with a total of 25 DCD donors. There has not been any stand down cases yet. Unfortunately, DCD are putting extra pressure on the capacity of the transplantation centers and some possible donations have been cancelled because the transplant team was not able to procure the organs. We are currently looking into this issue and hopefully it will be resolved quickly.

In June 2024, there was a political agreement to strengthen organ donation in Denmark through a national action plan. This contains initiatives on consent, hospital organization and living kidney donation. The details of the action plan are still being discussed and a change of law regarding the organ donor registry is yet to be passed.

Norway: Ragnhild Marie Sørensen

Donation rates in 2023¹ (2022)

- Realized donations by the method DBD (Donation after Brain Death) was **101** (103).
- Realized donations by cDCD (Controlled Donation after Circulatory Death) was **18** (6).
- **440** (418) organs were transplanted to **399** (382) patients.
- In recent years, the donation rate has been stable in Norway. The number of people on waiting list for organs has increased, especially for kidney transplantation².

cDCD - Controlled Donation after Circulatory Death

- **27** of the donor hospitals (a total of 28) report that they have approved the cDCD procedure, but only **12** have so far (not only in 2023) completed the procedure.
- The National Treatment Service for Organ Transplantation at Oslo University Hospital is responsible for coordinating with all the donor hospitals to ensure equal understanding of the procedure.
 - Oslo University Hospital has a department for organ donation and a department for transplantation. The department for donation has now been staffed to handle more cDCDs.

Local/regional differences in donation rates

- According to the Transplantation Act, the regional health authorities shall ensure that all potential donors can be considered and made available for donation within the health region.
- In Norway, probably for various reasons, there are some regional/local differences in donation rates.
- In 2007, the Norwegian Intensive Care Registry was established to document the potential for organ donations in Norwegian intensive care units. Several donor hospitals report the establishment of a system for identifying potential donors.
- In 2024, the regional health trusts have received an assignment from the Ministry of Health and Welfare to review the organization of the organ donation activities at the donor hospitals. The purpose is to identify all potential donors and prevent unjustified variation in the number of donors. The National Treatment Service for Organ Transplantation is given a coordinating role.

Reported activities in 2023

- The donor hospitals participate in a national **professional day** for donor-responsible doctors and nurses, under the auspices of the Norwegian Resource Group for Organ Donation (NOROD), and in NOROD's **education programs** step I and/or II.
- Several donor hospitals report on internal and regional **professional days**.
- Oslo University Hospital has:
 - arranged two **professional days** (2023) on organ donation and transplantation for all donor hospitals in collaboration with NOROD (step I).
 - offered an **e-learning course** on organ donation.
 - arranged a **memorial day** for relatives of organ donors from all donor hospitals. The purpose is to honour the organ donors and their relatives.
 - offered the next of kin to return to the hospital after two to three months for a **follow-up interview** with the doctor and nurse who were involved in the process. The purpose is to ensure that they receive answers to questions about the course of treatment, such as which organs have been donated. At the same time, a **letter of thanks** will be handed over on behalf of the transplanted patients.

European cooperation

- Norway participates in the meeting of the Council of Europe on organ trafficking - The Committee of the Parties (CoP) to the Convention against Trafficking in Human Organs (THO). Norway is the only Nordic country that have signed and ratified the convention, and present on the meetings³.
- Norway is also represented in the European Committee on Organ Transplantation (CD-P-To), and National Focal Points (NFPs) on transplant-related crimes.

A supervision of organ donation and transplantation

- In 2024, a supervision shall be carried out by the Norwegian Board of Health Supervision at the Oslo University Hospital. The purpose is to investigate whether the management at the hospital ensure that the requirements of the regulations are complied with in the case of organ donation and transplantation.

Organ donation from young children

- The Norwegian Paediatric Association works to promote organ donation from young children.

¹ Annual reports from donor hospitals and the transplant service 2023. [Sammenstilling av årsrapporter fra donorsykehus og transplantasjonsvirksomheten i 2023 - Helsedirektoratet](#).

² [Lengre ventelister for organtransplantasjon | Tidsskrift for Den norske legeforening \(tidsskriftet.no\)](#).

³ [Council of Europe Convention against Trafficking in Human Organs - Impact of the European Convention on Human Rights \(coe.int\)](#).

Sweden: Johan Nilsson (No CA present)

The number of donations has increased, with 258 donors recorded last year. It is challenging to pinpoint the exact cause of this rise or determine whether it represents a fluctuation in donation trends. While Donation after Circulatory Death (DCD) was introduced a few years ago, and has likely contributed, it cannot be considered the sole factor, particularly given the significant number of heart transplantations that have occurred.

A DCD heart transplantation program is currently being planned, with Gothenburg and Lund hospitals expressing interest in participating.

Finland: Marko Lempinen (No CA present)

The challenges faced are similar to those encountered by other countries, including the issue of underreporting of SAE and SAR, which remains a topic of ongoing discussion. In 2023 and 2024, over 300 kidney transplants were performed, along with a significant number of liver transplants. The DCD program for kidney transplantation is currently operational.

While there has been a slight increase in donors from the DCD program, it is still too early to fully assess the impact on the brain-dead donor population.

Iceland: Þórgunnur Hjaltadóttir

- We are working on changes to Heilsuvera, which is a public website where people can communicate securely with the health service, and among other things where people can opt out of organ donation. We are rewriting what is related to organ donation, hopefully for simplification and benefit. Today, people can completely opt out of organ donation or people can partially opt out ie. people can exclude certain organs. Today, you are asked to write in a textbox which organs you want to exclude but this will be changed so that people will have to tick in box/boxes, to mark which organs they want to exclude. This will increase clarity and facilitate statistics. Today, we cannot say with certainty which organs people want to exclude, which is certainly interesting numbers.

- A total of 4,700 people have opted out of organ donation, around equal numbers of men and women and this is about 1.6% of the population over the age of 18, but people under the age of 18 cannot opt out of organ donation. 2,225 persons have declared partial organ donation, twice as many women as men, (728/1.497) but this partial „opt out“ needs to be examined carefully in case of a possible organ donation, because often people write in the textbox something like "you can use all my organs", or "I would like to help as much as I can", etc. The most common organ people want to exclude are the eyes, which we do not take.

- We observed at Landspítala – our main hospital how the health staff check whether a patient has opted out from organ donation, i.e., if that possibility opens up. In the medical record, the doctors can see whether a patient is an organ donor or not, and how this is done was closely reviewed with the IT department and relevant employees.

- In Iceland we have not started DCD yet but the organ donation team at The National University Hospital is almost ready for the DCD process in cooperation with the organ donation team in Gothenburg. The Directorate of Health has been working with the Ministry of Health to examine the legal aspects of the project. The way it looks to us, we don't need to change the law, but this is under consideration and we will probably put in some rules with a clarification of the terms DBD and DCD. We hope that DCD organ donation can start later this autumn but there has not been any public debate about this yet.

- In terms of organ donation, this year has not been generous. In 2023, there were 10 deceased organ donors – that's an organ donation rate of close to 26 per million, but this year we've only had 2 deceased organ donations, that's an organ donation rate of about 5.2 per million. According to the chief physician of the intensive care unit, there have not been many possibilities, but two families have refused organ donation and two patients were judged unfit for organ donation due to heavy drug abuse.

7. Any other business

No additional items were proposed for inclusion under Any Other Business.

8. Next meeting.

The next meeting will be in Helsinki in November 6th, 2025.