

Nordic Transplant Committee

/ Nordic Transplant Committee / Minutes meeting No. 18 Sept 24, 2013 Oslo

Sept. 27, 2013

MINUTES OF MEETING

Meeting No: 18th meeting in the Nordic Transplant Committee

Time: Tuesday, Sept. 24, 2013 at 12:00-16:00

Meeting place: The Norwegian Directorate of Health, Universitetsgata 2, Oslo

Meeting participants:

National Health Authority representatives:

Norway: **Zaheer A.Rana**; **Camilla Closs Walmann**; **Torunn Janbu**. Norwegian Directorate for Health, Oslo

Finland: **Jaakko Yrjö-Koskinen**, Ministry of Social Affairs and Health.

Sweden: **Carin Franzén**, **Karin Dunér Lindqvist**, The National Board of Health and Welfare.
Olof Högrell, Utredningen om donations- och transplantationsfrågor,
Regeringskansliet, Stockholm,

Denmark: **Anne Cathrine Bollerup**, Danish Health and Medicines Authority, Copenhagen.

The board of Scandiatransplant:

(KH) Krister Höckerstedt, Helsinki

(HI) Helena Isoniemi, Helsinki

(LW) Lars Wennberg, Stockholm

(PDL) Pål-Dag Line, Oslo

(FG) Finn Gustafsson, Copenhagen

(RP) Runolfur Palsson, Reykjavik

Scandiatransplant:

(KAJ) Kaj Anker Jørgensen, Aarhus, Medical Director.

(BHP) Bo Hedemark Pedersen, Århus, Programmer.

1. Welcome:

Torunn Janbu, Helsedirektoratet, Norway welcomed everybody and excused that Jorunn Svendsen had become ill and could not participate.

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

Krister Höckerstedt was elected as chairman and Kaj Anker Jørgensen as writer of minutes.

3. Approval of minutes from meeting No. 17, 2012:

Minutes were approved.

4. Additional issues for the agenda from the participants:

There were no additional issues.

5. Presentation of the new Medical Director in Scandiatransplant:

KAJ presented himself saying that he had been Medical Director of Scandiatransplant for 10 months. This position is half time, the other half time he is the senior physician responsible for kidney transplantation at Aarhus University Hospital. KAJ then gave a short presentation of Scandiatransplant as it works today. PDL added that Scandiatransplant is important

because each country is too small to be able to give each patient the best treatment. You need a larger population than any one of the countries has alone.

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

• **Main transplantation and administrative issues**

Denmark: FG said the activity in Denmark is stable. The Danish executive order following the Danish law had been in the second hearing and it was stated by Anne Cathrine Bollerup that it had been in effect since 23th of May 2013. Regarding to the public reaction there has been a debate on altruistic donation especially driven by the patients' unions.

Norway: PDL told that the activity is high and especially the liver and pancreas transplantations have risen. The donation rate is over 23 per million. There is ongoing work on implementing the EU directive also in Norway.

Sweden: LW told that donation rate is about 15 per million. There is some variation in the country. The law has been implemented and the SAE/AE have to be reported and are reported. Transplantation has been done with altruistic donors, about 10, these are a little bit more complex than ordinary living donor transplantations. There is a problem in having the data from Swedish citizens in Scandiatransplant in Aarhus, since it may not be completely legal according to Swedish law. The people from the competent authorities in Sweden (Socialstyrelsen) told about their activities where they are making a report of the activities, guidelines for donors, training of coordinators and discussing compensation for living donors. Olof Högrell from Svenska Donations- och Transplantationsutredning could also tell that they are analysing the Swedish legislation on patient integrity to secure an efficient exchange of data with, among others, Scandiatransplant. People from Socialstyrelsen gave a presentation which is sent out with the minutes.

Finland: Jaakko Yrjö-Koskinen gave a presentation which will also be sent out with the minutes. HI told us that donation rate was 19,7 per million and had increased in the last year. The increase was due to structural changes in Helsinki. Last year there were 310 organ transplantations in Finland. Last year they made 8 pancreas transplantations and this year they have already made 7. They have done 4 intestinal transplantations.

Iceland: RP told us that in Iceland there were 3 donors per million population per year. They have done about 6-12 living donor transplantations per year. They did not have any formal competent authority, but this was now undertaken by the Medical Director of Health. Transplantations with deceased donors are done in Gothenburg.

7. EU Directive on Organ Transplantation

Implementation of the EU Directive in the legislation of the three member states and Norway and Iceland:

Finland: Jaakko Yrjö-Koskinen said that the directive had been implemented in May 2013. The inspecting authority had been defined. Finland does not need big changes to comply with the directive. They are expanding the training of the people involved.

Denmark: Anne Cathrine Bollerup told us that the law became effective 15th of August 2012 and "bekendtgørelsen" (the executive order) became effective 23th of May this year. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the the implementing directive 2012/25/EU. . The inspection process has not been put into place yet.. Anne Cathrine Bollerup told about the NOTIFY (Exploring Vigilance Notification For Organs, Tissues and Cells) project on SAE/SAR. Attached to the minutes are examples of events in organ transplantation from the booklet NOTIFY

Sweden: Everything has been implemented except, possibly, some issues regarding the exchange of data as said before.

Norway: Waiting for new regulations.

Iceland: Waiting for EEA

LW then gave a short presentation of a suggestion from Scandiatransplant on SAE/AE. The presentation is attached to these minutes. The suggestion was, that since organs are transported across borders in the Nordic countries, there is a need for the same definitions of SAE/AE and an agreement on which should be reported. The Scandiatransplant board offered to make a list of what they think should be reported. This should then go to the competent authorities for acceptance. It was suggested that if this list was accepted, Scandiatransplant could log these SAE/AE. This issue will be revisited in the next NTC meeting.

8. Scandiatransplant

- **“Document on Scandiatransplant” – Data Security.**
- **Comments from each country**

The newly written document on Scandiatransplant had been sent out with the invitations for the meeting but not all competent authorities had read it. KAJ shortly went through it. The document was meant as a presentation of Scandiatransplant and especially for the use of the competent authorities, when they were talking to their IT-specialists. After that BHP gave a presentation on the data security system in Scandiatransplant. This presentation is attached to these minutes.

9. Transplantation of non-Nordic patients with organs from Nordic countries/non-Nordic countries:

KAJ gave an overview of the Estonian situation. Estonia had applied to become a member of Scandiatransplant, but the application was turned down. A new cooperation stated that Scandiatransplant recognizes Estonia as an OEO which we cooperate with. This has been in effect since January and in that time 23 organs have been exported to Scandiatransplant from Estonia, but there has been no organs exported from Scandiatransplant to Estonia.

10. Patient Mobility Directive and Transplantation:

Krister Höckerstedt told us that organ allocation and transplantation is outside the scope of the cross-border directive. Despite this the people in the commission are discussing if everything else related to transplantation is within the scope of the directive. This is under discussion.

11. Law suits in German transplant centers:

KH showed a presentation giving an overview of the scandals especially in liver transplantation in Germany. The presentation is attached to these minutes.

12. Any other business:

There were no other issues.

13. Next meeting September 2014 (Stockholm?):

It was decided that the next meeting should be in Stockholm on September 30, 2014.

Writer of minutes: Kaj Anker Jørgensen