SCANDIATRANSPLANT

Minutes of Meeting with representatives of National Health Authorities and representatives from the Scandiatransplant board and office and lawyers from Central Denmark Region

TIME: April 16, 2012 from 13:00 - 16:00
A light lunch between 12:00 - 13:00

PLACE: The National Board of Health, Islands Brygge 67 (entrance from the parking place), Copenhagen S, Denmark.
Meeting room 502 (5. floor)

1. **Welcome and introductory remarks, Krister Höckerstedt:**
   This is the follow-up meeting of the meeting 12.12.2011 in Stockholm with the purpose to find out how the national authorities in the five Nordic countries will implement their EU Directive on organ donation and transplantation and how to find the interactions between the Scandiatransplant office, Scandiatransplant data registration and the national authorities.

2. **Election of writer of the minutes**
   Niels Grunnet elected.

3. **Approval of the minutes from December 12, 2011:**
   The minutes approved. Höckerstedt chaired carefully review of some of the most important issues from these minutes.
   - That data processing in the Scandiatransplant database has been notified under the auspices of central region Denmark and that all processing of personal data in the EU and the EØS countries are considered safe in relation to the present Scandiatransplant database. Informed consent is not formally registered in all the five Nordic countries apart from using living organ donors. Patients being put on the waiting list for an organ transplantation are asked in all the countries if they will receive such a treatment, but only Norway has a formalized system for documentation of this. The national health authority in each country has to define demands for behaviour at the clinical departments.
   Concerning the present Scandiatransplant database, the region of Central Denmark is a controller, and Scandiatransplant is the operator.
   The system for reporting of severe adverse events (SAE) and serious adverse reactions (SAR) have not been clearly defined in each of the countries. The problem is to define the cutoff line between minor events and those qualifying to be named serious, and therefore should be treated according to the recommendations from EU and the national adoptions.

4. Housekeeping information given by BjørnUrsin Knudsen, including the new organisation of "Sundhedsstyrelsen":

information given by Bjørn Ursin Knudsen. Anne Marie Vangsted from the new fusion of Danish Medical Agency and national board of health given the name Danish Medicines and Health Authorities gave a short overview of the new organisational structure. Three of the present participants come from the previous Laboratory of Inspection. They are experienced in managing and inspectionary relation to the EU Directive and law concerning blood and the same for tissues and cells. Therefore it is now under definition of who shall do what in relation to this new EU Directive on Transplantation.

5. Adoption of the Agenda/additional issues and short introduction of new participants:

A short presentation round.

Tore Ryberg, lawyer. Louise Gjørup, lawyer. Birgitte Bjerre, physician. Anne Marie Vangsted, chief function for audit issues and more (all from Denmark). Kari Steig, lawyer from Norway. Ewa Leinonen, lawyer from the Finnish medicines' agency. Søren Schwartz Sørensen, nefrologist, chief physician, former board member of Scandiatransplant, now adviser for national health authority, Denmark. All other participants have been present in the earlier meetings.

6. Presentation of Scandiatransplant's approach to 2010/53/EU:

Niels Grunnet presented a text (distributed to the participants).

To the meeting participants April 16, 2012:

The Cooperative work within the organisation Sctp for 43 years has established improved help to Nordic patients in need of an organ transplant.

This is the fact due to

- a clear cut traceability
  from donor do recipient and vice versa. It is possible to use Sctp-ID-no, a unique no. for the donor and for each of the recipients.
- due to a common waiting list for an organ transplant based on a population of 25 million it is possible to give better help to:
  - immunized patients
  - urgent patients
  - special subgroups of patients
- due to the cowork almost none of organs available for transplantation will be lost ! This can be the case if the pool of waiting recipients is too small,due to blood group and HLA incompatibilities.

Therefore, we from the medical transplant community will recommend the continuous use of Sctp as the place

- to register the donors and transplantations,
- to continue to work out the rules for organ exchange between the Nordic countries
- to run rhe connections with the present and new European Organ Exchange Organisations (OEO)
- to make annual reports,
- to work together with the national health authorities, who shall register SAE (Severe Adverse Events) and SAR (Severe Adverse Reactions).

The National Health Authority also have the responsibility against EU, shall have a register over licensed clinical departments, and health care personel, and laboratories doing the tests.

If we can agree on these statements we have to define the roles and duties of
- The National Health Authority
- the transplant centers
- the office of Scandiatransplant (Sctp).

(Sincerely, Niels Grunnet, Medical Director, Sctp.)

Frank Pedersen presented the Scandiatransplant datasystem on the screen: An actual case showing traceability between organ donor and recipients.
The benefits of one common waiting list per organ for the five Nordic countries giving better offers to individual patients also demonstrating the increasing of the possibility for a Nordic patient to receive an organ and that this system will enable the transplant centers to have maximum use of transplantable organs within the Nordic countries only very few organs are in a ten year period sent outside the five Nordic countries. This was demonstrated for lungs, hearts, livers, kidneys. All participants had possibility to ask for details.

7. 2010EU Directive 53. Implementation of mandatory data in national registries by August 27, 2012.

- Present situation in the Nordic countries:
Responsibility of the national authority?
Responsibility of the transplant centers within the Nordic countries?
Responsibility of the Sctp-organisation?

Finland: The new legislation is in draft, not nominated yet of Finnish agency. Meeting planned week 17 between the agency and the transplant center in Helsinki. The registry at Helsinki University Hospital is maybe enough for the agency, but these data are exported to the Sctp system and Helsinki have use of the Sctp datasystem in the exchange of organs between transplant centers within the five Nordic countries.
In Finland and Norway no new registers of waiting list patients are planned.
In Finland the Organ Transplant Registries of the Helsinki University Hospital have been named by the national authorities to form the National Transplant Registry. New minor issues stated by the EU and the competent authorities are to be included. Additional issues stated by the EU-53/2010 Directive are going to be incorporated in the present law (20120)
Between the people at the transplant center and the Health Authority there is a common understanding of how these new directives can be implemented. Several debates have been done and are ongoing.
From Norway it is stated that it is not only a matter of one registry, but many registries, fx. the registers within the Sctp system, but in addition one has to have a register of SAE/SAR. Another one on accreditation organs and departments. Another one on licensed persons working with organ transplantation. And finally registry or documentation of patient information matters. So, it is a problem of trying to keep the tongue in the right place. In Norway they have some ideas of the way of solving these issues, but it is not finalized yet. Registries are legal provisions and the implementation of the EU Directive on Transplantation is a good time to clear out some unclear issues.
In Sweden there is now a proposition out on the new law. It will be exposed for exernal review with a conclusion in mid-May. In Sweden they also have the concern of the issues of personal data protection which as stated elsewhere comes from EU Directives from 1996, so this is an old issue which especially the lawyers would like to take care of in connection with the present implementation. Health authority in Sweden have had meetings with the personnel from the transplant centers. It is stated at this meeting that it is not the intention from the

Swedish health authority to interfere or to destruct the cooperative work already established within the Scandiatransplant organisation and association.The problem is how to solve the additional issues being a consequence of implementing the EU directive 53.
Denmark: The Danish law as a consequence of the directive 53 has passed the acceptance procedure in the parliament. Numerious clarifications are on the way in the national health authority. Vangsted stated that a common contract between each country and Scandiatransplant and the elaboration of the issues of the directive is very advisable and recommended. It is stated that the report to EU shall be sent every third year, first time August 2013 and after that in three-years intervals.
From Iceland new persons are involved in administration at the health authority. 2 meetings have been held in the present five-year period with Gothenburg as the co-working transplant center. All deceased donor transplantations are done in cooperation with Gothenburg, Sweden. Iceland do living kidney donor transplantations themselves.
There is a common debate of how to fulfill the 24/7 duty of reporting SAE/SAR. It is recommended and concluded that this can only be the duty of the personnel at the transplant centers, not Scandiatransplant and not the health authority, but the health authority has an obligation to follow-up and give feed back on the accummulated observations of SAE/SAR.
The Scandiatransplant datasystem expects to fulfil the demands for fields covering annex A of the Directive. These data it should be possible to report to the Scandiatransplant datasystem by mid-August 2012. From several participants it is stressed that it is very necessary that reporting of SAE and SAR are kept operationable and reasonable with respect to what has to be reported. The way of the patient identification in the Scandiatransplant datasystem was discussed. Norway use donor code and an Sctp donor number. Due to safety of the treatment it is necessary to have a patient identity. In Norway they have limited the access to the personal data to the tissue typing laboratory and can therefore use the Scandiatransplant datasystem by codes and donor number. So one way to solve the problem is to limit the access to the data being personal referable (enter personal register number). One country stated (from Sweden) it was mentioned that one could maybe use initials only and then later on solve the problem towards the personal data law. However, this is not optimal. Today it is so that one center can see own center data, or one country can only see own country's data.
In the Scandiatransplant access there are different levels, superusers at the office, users that can register data and others that only can have a look at some data. It is concluded that it is necessary to have some personal identification data not to violate the register in Scandiatransplant because something can happen to a patient up to many years after the transplantation. In principle it is needed to have a lifelong data registration about the transplanted patients.
The main rule is that one shall only have access to the data on patients that you need. Therefore it is very necessary to clarify who has access and for what purpose as already done in the Sctp data system. It shall be clarified how Sctp limit access for some people.
Another possibility is to delete personal, referable ID and only use Scandiatransplant ID number after some time (some years)?
The implementation of Directive 53 will demand illustration of what is Sctp system and what it is necessary to build beside that. That discussion will go on in the near future in Denmark and also in the other Nordic countries.

8. Scandiatransplant Registry of organ transplantation using living donors.

In 2003 it was decided to implement the register on living kidney donors from Norway into the Scandiatransplant datasystem which is in place now. All centers use the register for living kidney donors, so this is a facility available. This facility was created based on an ethical conference in Amsterdam approx. 2001 followed by a meeting in Fornebu in 2003 and the Norwegian register for living kidney donors was then integrated in the Scandiatransplant system as a friendly agreement. There has been much talk on mandatory fields, but it is clear

that a minimum amount of data is required. Actually more than data from 4700 living donors are registered in the register, however some have to be reported "by hand" to complete the database.
It is asked what the data are used for, research? The answer was no, but used for quality control. Each center can only see data from own center. Again in the Sctp system we have A-users, B-users and X-users being superusers. Partipants ask to the security rules for the data. It is a socalled SSH-system in the old system and SSL in the new system.

9. Agreements?/Contracts?

Sofar we have had two special meetings between the health authorities and Scandiatransplant. It is still too early to make contracts, but all the health authorities are working fast in being ready to implement the EU Directive by August 27, 2012. The next meeting in the Nordic Transplant Committee is scheduled to be September 18, 2012 in Helsinki, and this meeting can be a follow-up meeting to this meeting today. All the present health authorities expressed that they will continue to use the Scandiatransplant datasystem as we know it today.

10. Conclusions

Continued co-work within the Scandiatransplant organisation with the use of the system as we know it today. The implementation of the EU Directive will be followed and will require working out contracts between several partners.

Writer of minutes: Niels Grunnet