



**MINUTES OF THE FIRST MEETING OF THE COMPETENT AUTHORITIES
ON ORGAN DONATION AND TRANSPLANTATION
6 – 7 SEPTEMBER 2010**

The First Meeting of the Competent Authorities on Organ Donation and Transplantation was convened on 6 and 7 September 2010. All Member States except Hungary (excused - invitation received late) were present at the meeting; were also present: experts from Norway, Croatia, WHO and the Council of Europe Eurotransplant and Scandiatransplant.

1. WELCOME AND INTRODUCTORY REMARKS

The Chairperson welcomed the delegations. The aim of the meeting was to amongst others present the newly adopted Directive, explain the next legislative steps, have an exchange of views on the National Action Plans and present the progress of the two technical working groups of the Action Plan; indicators and deceased donation.

2. INTRODUCTION OF NEW PARTICIPANTS

Each delegation presented a brief overview of its structures, related responsibilities, and underlined the main developments since the last meeting in November 2009.

3. DIRECTIVE 2010/45/EU

Presentation of the Directive

The Commission made a short presentation, introducing the key articles of the Directive.

Transposition

Directive 2010/45/EU is to be transposed by 27 August 2012.

Member States are advised to contact the Commission on transposition in case of doubt. In the Commissions' experience, early contact and consultation can avoid burdensome administrative/ procedures afterwards. The Commission is available for explanatory meetings.

Delegated measures and Implementing Acts; forward planning.

A brief introduction on the new procedures on delegated and implementing acts (Articles 290 and 291) was given by the Commission. It was clarified that the following elements shall be further developed either through delegated or implementing acts:

- (1) part B of the Annex on organ and donor characterisation (through a delegated act);
- (2) uniform rules on traceability of organs, when organs are exchanged between Member States (through an implementing act);
- (3) uniform rules on vigilance operating procedures, when organs are exchanged between Member States (through an implementing act);
- (4) procedures for the transmission of information on organ and donor characterisation (through an implementing act).

FR, ES, IT, PL, DE, SL, UK, NL and Eurotransplant agreed to help the Commission in the preparatory work for implementing and delegated acts.

Reporting obligations and transposition

The Directive requires Member States to report before 27 August 2013 and every three years on activities taken in relation to the Directive and experience gained from implementation.

The Commission has to submit before 27 August 2014 to EP and Council a report on implementation.

4. TECHNICAL WORKING GROUP ON INDICATORS

4.1. Overview of Activities

The Commission presented the activities undertaken by the technical working group on indicators:

Meetings:

- 4 March 2010 to draft questionnaires and data requests
- April: completion and distribution of questionnaires
- May-June: replies and consolidation of results (ONT, EC)
- Meeting 8 July 2010 to discuss first results

Participants: NL, BE, FR, ES, PL, SE, UK, IT, DE, SL, Eurotransplant, Scandiatransplant

Discussion Areas: Donation, Waiting lists, Allocation, Transplantation, Health outcomes, Healthcare resources

4.2. Presentation and discussion of Consolidated Results on Indicators

The objective was reemphasized: benchmarking Member States' (MS) different activities in organ donation and transplantation, to identify learning opportunities and good practices. There is no need for highly developed and detailed exercises, but rather for an exercise where as much Member States as possible can participate.

The agreed working principles are:

- Valuable outputs and feasible inputs (insights for participants + limited/easy data inputs, allowing all countries to participate);
- A comprehensive and simple list of indicators with a high-level scope (cover all relevant aspects of donation and transplantation + limited nr of high-level indicators, where desired, some can take the exercise a level deeper);
- Build on existing work and data, with existing quality (control), avoiding duplication;
- Work with agreed definitions and nominators;
- Anonymization of results where desired

It was reemphasized that this is work in progress. Participants were asked for comments and suggestions to help further develop this exercise during the next years. Overall, an ambitious final objective should be laid down, while looking for a step-by-step approach that is feasible for all Member States towards achieving this objective.

The final objective is in first place understanding and improvements of daily activities, not just developing an exercise with exact scientific data.

Different participants of the Working Group presented the six sections covered by the indicator exercise: donation, waiting lists, allocation, transplantations, health outcomes and resources.

The participants gave comments on the presented data and direction for the further development of the exercise. The Commission will prepare a list of key points for the next discussions in the Working Group.

The discussion on indicators ended with the following conclusions:

- All Member States will take another look at their national data and provide the Commission with eventual comments by 15 October. The Commission will make a last update, concluding this 2010 exercise.

- There is more need for data collection, in particular for health outcomes. All Member States will reflect on how they can collect more 2010 data for the 2011 exercise. In order to guide/support these national reflections, the Working Group Indicators will prepare the list of data needs during its next meeting.
- The Working Group on Indicators will look at how to follow up to all comments and ambitions. In particular the Group will try to develop a long-term ambition, allowing to collect more data and to make more in-depth analyses for the different fields. For example by including the work on the critical path and by redrafting the qualitative questionnaires.
- The practical ideas that were brought up mainly relate to cross-border collaboration (a) establish cross-border programmes for transplants and (b) to create a list of EU centres of excellence for specific types of complicated transplants. The practical follow-up and political impact will be discussed in the next Working Group on Indicators.
- As the data is still subject to much improvement and discussion, it was agreed that the results of the 2010 exercise can not become public and are to be dealt with in a confidential way.

5. SET OF NATIONAL PRIORITY ACTIONS

5.1. Presentation of Set of National Priority Actions

The following Member States presented their National Action Plans (NAPs):

Portugal

Germany

Romania

It was agreed to foresee some place in every future Competent Authority meeting to give Member States the opportunity to present their activities.

6. TECHNICAL WORKING GROUP ON DECEASED DONATION

6.1. Overview of Activities

The Commission presented the activities undertaken by the technical working group on deceased donation:

Meetings:

- 29 September 2009
- 4 March 2010 and
- 8 July 2010-08-19

Participants: NL, BE, FR, ES, PL, SE, UK, IT, DE, SL, Eurotransplant, ScandiTransplant

Topics: (1) Manual on transplant coordinators, (2) Prepare future areas of action.

6.2. Manual on Transplant Donor Coordinators

The representative from the Department of Health-UK presented the evolution of the working document for setting-up a system of transplant donor co-ordinators ("Manual on Transplant Donor Coordinators").

The objective of this "manual" is to build on Member States' experience in order to help other Member States set up and eventually run a system of donor coordinators. The document does not aim to compare the different systems neither to establish a best practice nor to interfere with already existing organisational structures. It was discussed and clarified that the document will not be in any way binding for the Member States. Several comments were received with regard to the scope, structure and terminology of the document. UK delegation kindly volunteered to prepare a second version of the document capturing the comments made by Member States during the meeting.

Action: All Member States to send their comments and contributions on the manual (Version 9 of 13 August 2010) by **30 September**.

7. AREAS FOR POTENTIAL ACTION

7.1. Living donation

Scandiatriplant presented a working document on living donation with the contributions of NL, ES and SE. The main objectives of the document were the following:

- demonstrating the value of living kidney donation (to politicians and medical profession), as an additional mechanism to increase the number of available kidneys;
- providing training, guidelines, general information on how to set up a living donor programmes.

It was agreed to create an additional technical working group on living donation. This new technical working group would use existing and future findings of projects like EULID, ELIPSY and ODEQUS.

NL, UK, FR, DE, SE, CY, ES, Scandiatriplant, NO and the Council of Europe agreed to take part in this technical working group

7.2. European mapping of organ exchanges

An update of the status of the cross-border directive was provided by the Commission. It was pointed out that the Common Position will be transmitted to the European Parliament on 20th September 2010 and the Second Reading will then commence.

The COORENOR project was presented by the project co-ordinator; particular reference was made to work package 4 which will include a first map/overview of cross border organ exchanges.

It was agreed not to take concrete action for the moment. The issue is to be re-discussed once the negotiations of the cross-border Directive and the conclusions of the COORENOR Project are finalised.

7.3. Collaboration of ICU doctors and transplant coordinators

A document prepared by UK, SL, NL and ES was presented in order to increase collaboration between Intensive Care Unit (ICT) doctors and transplant coordinators. Proposals in the document included the following:

- Develop minimal data set to audit performance of each ICU;
- Stimulate national protocols on donor management;
- Design model with the main tasks of donor coordinator/ intensivists;
- International training programmes for intensivists and ICU staff.

The Commission indicated that the 2011 Health Programme could potentially deal with the collaboration of ICU doctors and transplant coordinators based on the conclusions of the aforementioned document.

7.4. Extended donor criteria (ECD)

The Spanish representative presented a document on EDC jointly prepared by ES, DE and Eurotransplant. The paper suggests the following EU action on the issue:

- Definition of ECD in the EU context;
- Monitoring the use of ECD and the outcome of recipients from ECD in the EU;
- Sharing of best practices in the use of ECD;
- Developing recommendations for the use of organs from ECD in the EU;
- Ethical considerations related to the use of ECD, including key elements for informed consent for recipients of ECD;
- Set-up an EU registry collecting data on ECD and allowing analysis.

The German experience on the issue was also presented.

It was decided that the starting point should be the EFRETOS project. This priority should therefore be put on hold for the time being. Once the project is finalised, the issue will be re-discussed and explore how it can best be addressed.

8. PRESENTATION OF EXISTING AND FUTURE PROJECTS ON ORGANS - EACH

8.1. Introduction of EACH activities

The Health Programme and the activities of the Executive Agency were presented to the participants; in particular the presentation covered the majority of projects in the field of transplantation listed below.

8.2. Calls for Proposals and Tenders

8.2.1. *ETPOD*

8.2.2. *EULID*

8.2.3. *ELIPSY*

8.2.4. *COORENOR*

8.2.5. *ODEQUS*

8.2.6. *EFRETOS*

Remaining projects, tenders and actions (i.e. European Donation Day, ELPAT conference) can be presented at future meetings.

9. AOB

- West Nile Virus (WNV): The Commission presented briefly the situation with regard to the WNV cases in Portugal, Romania, Hungary, Italy and Greece as well as the actions taken. It was recognised that the area of organs is different than blood, tissues and cells and that further discussion is required as to how similar cases should be handled in the future. This discussion can take place under the frame of the implementing act on vigilance operating procedures.

10. CONCLUDING REMARKS AND ACTIONS:

- Create additional technical working group on living donation. Participation: NL, UK, FR, DE, SE, CY, ES, Scandiatransplant, NO and the Council of Europe.
- Commission to start preparatory work on delegated measures and Implementing Acts with the assistance of FR, ES, IT, PL, DE, SL, UK, NL and Eurotransplant.
- Regarding the results on indicators, Member States to verify their national results and send comments by 15 October to Stefaan.Van-der-Spiegel@ec.europa.eu. Commission will then do the final correction for this first (2009) version of the indicator exercise.
- On the **manual of Transplant Donor Coordinators**, the UK will prepare a second version of the document including the comments made by Member States by 30 September.