EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Brussels,
SANCO C6(2008)D/360020/EFZ/ci

2ND NATIONAL EXPERT MEETING ON ORGAN DONATION AND TRANSPLANTATION AT COMMUNITY LEVEL

BRUSSELS 20 NOVEMBER 2007
9:30 – 17:00

SUMMARY REPORT

The second national expert meeting on organ donation and transplantation at Community level was convened on 20 November 2007 under the Chairmanship of Mr Tapani Piha (TP), Head of Unit SANCO C6.

26 Member States were present at the meeting and also representatives of the Council of Europe, Eurotransplant and Scandiatransplant. The list of participants is appended in annex 1.

1. Welcome and introductory remarks

The Chairman TP welcomed the delegations. The aim of the meeting was an exchange of views between technical experts of the all MS and relevant stakeholders, in order to discuss the working paper on an **action plan** for a strengthened cooperation between Member States: discussion was focused on the priorities top include in the plan and on the best mechanism of coordination. This action plan should be seen in combination with a legal instrument on quality and safety. The second objective is to report and update the group on the work of the working group on quality and safety on organ donation and transplantation

2. Adoption of the agenda

The agenda was adopted without objections or addenda

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3. Follow up of the Commission Communication on organ donation and transplantation

The Commission informed about the follow up steps after the adoption of the Communication on organ donation and transplantation.

- The Portuguese presidency of the Council has proposed draft conclusions for the health Council on 5/6 December.
- The European Parliament has appointed Mr Adamos Adamou (CY, GUE-NGL) has been appointed rapporteur for the communication on organ donation. The following work plan was announced a provisional time table for the EP opinion, adoption in ENVI committee on March and on the Plenary in April.
- The Commission has introduced in the legislative work programme (CWLP) 2008, the two initiatives on organ donation and transplantation. (Action plan + Directive) as priority actions.
- The Commission will create a key Stake holder group to consult relevant European associations in the field.

4. Introduction to document on a future action plan for a strengthened cooperation between Member States: Priority actions.

With this working document the Commission is seeking to set out a more detailed list of priority actions specifically tailored to the field of organ donation and transplantation. Some of these actions will require EU involvement and direct action, whereas other are supposed to be included in National Action Plans. In the latter, implementation of the actions is mainly under the responsibility of the Member States, having the Commission the role of coordinating and facilitating this process.

The document prepared for this meeting contains a list of five objectives, and 12 priority actions (divided in sub actions), which should serve as a basis for discussion. The objective today is to continue the discussion on which of these actions should be incorporated in the document.

5. Discussion on the priority actions by objectives

The first objective in the document was *to* ***reach the full potential of deceased donations in all Member States.*** This objective had three priority actions:

- Priority action 1: Promote the role of transplant donor coordinators in every hospital where there is a potential for organ donation.

This priority action was subdivided in the following actions:

a) Action 1.1 Incorporating in the national action plans the objective of gradually appointing transplant donor coordinators in every hospital with an intensive care Unit. Design indicators to monitor this action

b) Action 1.2 Promote the Establishment of international recognised standards for transplant donor coordinators programmes

c) Action 1.3 Promote the Implementation of effective training programmes for transplant donor coordinators

d) Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators

e) Action 1.5 Recognise the role of the donor transplant coordinator in the EU legal framework.

The majority of the experts agreed in the efficacy of this initiative. Some experts considered, however that this could not be a part of a European legal framework but achieved through national actions.

The denomination of this "key" person raises also some discrepancies, some experts considered a better name "transplant" coordinator. Others experts thought that "donor transplant" coordinator was a better denomination because it underlines the importance of the donation process.

- Priority action 2: Promote Quality improvement programmes in every hospital where there is a potential for organ donation

This priority action was subdivided into the following actions:

a) Action 2.1 Incorporate in the national action plans the objective of gradually put in place quality improvement programmes in every hospital where there is a potential for organ donation. Design indicators to monitor this action.

b) Action 2.2 Promote the accessibility to specific methodology on quality improvement programmes

c) Action 2.3 Recognise the role of the quality improvement programmes in the EU legal framework

The majority of the experts agreed in the efficacy of this initiative. Again experts considered that this should be achieved through national actions. A clear definition of quality improvement programme is needed in the opinion of the experts.

Some experts proposed to introduce the "conversion rate" as an indicator for this priority action.

For some experts it is important to differentiate the donation process and its results from the transplantation process, other experts considered that these two processes (donation and transplantation) should be always intimately linked.

- Priority Action 3: Promote the use of expanded donors

This priority action was subdivided into the following actions:

a) Action 3.1 Promote common definitions of terms and methodology to assist in determining the acceptable levels of risk in the use of expanded donors.

b) Action 3.2 Development of guidelines for establishing the best use of this type of donors

Some experts considered that it would be very difficult to build a consensus on guidelines for the management of expanded donors and suggested to drop this point from the action plan. Others suggested that given its complexity this should be a long-term exercise linked with the evaluation of post transplant results.

The second objective in the document was ***to promote the implementation of programmes of living donation following best practice.*** This objective has one priority actions:

- Priority Action 4: Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors

This priority action was subdivided into the following actions:

a) Action 4.1 To create a consensus on European common standards regarding legal, ethical, protection in relation to organ living donors.

b) Action 4.2 Incorporating in the national action plans the promotion of altruistic donations programmes from living donors, on the basis of appropriate safeguards concerning the protection of the living donors and the prevention of organ trafficking.

c) Action 4.3 Promote registration practices regarding living donors to evaluate and guarantee their health and safety.

d) Action 4.4 Recognise and ensure the protection of living donors in the EU legal framework.

The majority of the experts agreed in the interest of this initiative. Some experts raised ethical questions related with this activity and insisted the need to underline the character altruistic of these programmes. Differentiation between directed and non-directed living donation should be made. Also between the type of donated organ. It was also mentioned that these programmes should not compete with deceased donation programmes.

One of the priorities in the opinion of experts should be the protection of the living donor, including the follow up of the donor's health. The work of the future Council of Europe on the future recommendation of living donation and the convention of Oviedo were recommended to be taken into account.

The third objective in the document was ***to Increase Public awareness on organ donation.*** This objective has three priority actions:

- Priority action 5: Promotion of donation in specific groups and populations.

This action was supported by the experts. Some experts will share with the groups their national experiences on promotion of donation in specific populations/groups.

- Priority Action 6: Facilitate the identification of organ donors across Europe in order to increase organ availability

This priority action was subdivided into the following actions:

a) Action 6.1 Design, feasibility and assessment study on the implementation of a European donor card

b) Action 6.2 European Public campaign on the basis of the European donor card.

Most of the experts were critical about the idea of a European donor card, because the potential implications on the opting-out consent systems and because these cards seems to have low efficacy in increasing donation rates. Others mechanisms of achieving this priority action and different ways of implementing European elements on such cards should be explored.

- Priority Action 7 Increase public awareness and improve communication skills of professionals

This priority action was subdivided into the following actions:

a) Action 7.1 Incorporating in the national action plans the recognition of the important role of the mass media and the need to improve the level of information of the population on these topics

b) Action 7.2 Promote training programmes oriented to improving the knowledge of health professionals and the media skills about transplantation issues

c) Action 7.3 To implement at national level (competent authorities) a transplantation communication line, periodic meetings with journalists and opinion leaders and management of adverse publicity.

d) Action 7.4 Promote training programmes oriented to improving the knowledge of judges and legal community about transplantation issues

There was an agreement on the appropriateness of this priority action. Working with health professionals should a priority in the opinion of many of the experts. Some of the initiatives proposed, such the communication line, should be better assessed in terms of cost effectiveness.

The forth objective in the document was ***to support and guide transplant systems to be more efficient and accessible***. This objective has three priority actions:

- Priority Action 8: Enhancing the organisational models of organ donation and transplantation in the EU member states.

This priority action was subdivided into the following actions:

a) Action 8.1 Ad hoc recommendations of the committee of experts to Member States on the basis of the regular reporting to be included in the national actions plans.

b) Action 8.2 Promotion of twinning projects and peer reviews

c) Action 8.3 Assessment on the use of structural funds and other community instruments for the development of transplantation systems

d) Action 8.4 Promoting the development of transplant centres of excellence

It was a general agreement in the principle of this priority action, it should be however better clarified how this will be organised in practice. The concept of centres of reference as foreseen in the context of health care discussions was also clarified.

- Priority Action 9: Promote EU-Wide agreements on issues related to transplantation

This priority action was subdivided into the following actions:

a) Action 9.1 EU Wide agreement on basic rules for internal EU patient mobility and transplantation.

b) Action 9.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patients

c) Action 9.3 EU Wide agreement on monitoring organ trafficking

d) Action 9.4 EU Wide agreement on common priorities and strategies on future research programmes

Common agreement on the need to have an exchange of views and common understanding on most of the issues proposed. These are problems common to all transplant systems and should have a common and agreed approach. Some experts considered that research programmes should be taken out of this priority action.

- Priority Action 10: Facilitate the interchange of organs between national authorities

This priority action was subdivided into the following actions:

a) Action 10.1 Guidelines for systems for offering surplus organs to other countries can be evaluated

b) Action 10.2 Guidelines for the exchange of organs for urgent patients and difficult-to treat patients

c) Action 10.3 Design IT tool that could support the previous actions

Some experts underlined that the term guidelines should be avoided, as it will difficult to reach a consensus on specific procedures. The majority of the experts believed that a EU centralised system should not be an objective, however it was recognised that regional cooperation is needed for a better effectiveness of the systems and vital for small Member States. This cooperation should be promoted without imposing unnecessary obligations.

The forth objective in the document was ***to improve the quality and safety of organ donation and transplantation.*** These actions will complement the EU legal framework by placing in the action plan those actions that are better done in a cooperative basis than through a binding instrument.

This objective has two priority actions:

- Priority Action 11: Evaluation of post transplant results.

This priority action was subdivided into the following actions:

a) Action 11.1 Develop common definitions of terms and methodology to evaluate the results of transplantation

b) Action 11.2 Development of register or network of registers to follow-up on organ recipients

c) Action 11.3 Elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results.

The evaluation of the quality of transplantation was considered very relevant by the experts, it was also recognised the complexity of the task and the need of resources for accomplish it. It was also recognised that existent registers that can not compare their results given there is not common methodology and terminology.

Some experts recommended to drop point 11.3 as it could interfere with national allocation rules.

- Priority action 12: promote a common accreditation system for organ donation/procurement and transplantation programmes.

Some experts proposed to substitute accreditation by auditing and include the concrete requirements for these auditing in the action plan rather that in the legal framework.

The Commission asked the participant to submit any comment on the priority actions by 17 December.

6. Report of the working group on quality and safety

The Commission presented the working document discussed in the working group on quality and safety and reported back to the group the main conclusions of the group. Summary Report of that meeting attached to this document (Annex I).

The Commission will present a new working document to the next meeting of the quality and safety group which will take place in the first quarter of 2008.

7. Method of coordination

The expert invited by the commission introduced how the open method of coordination (OMC) between MS could work. She suggested that this could be one of the options as a mechanism of coordination. It would be based on agreed objectives, common indicators and it will have a regular reporting from MS, evaluation and recommendations.

One expert considered this method could be burdensome for national administration. It will be important to assess correctly the impact of the OMC. Other participants agreed with the idea of putting in place an OMC tailored to this field and more flexible that the classical OMC.

8. Conclusion of the meeting/next steps

It was concluded at the meeting that there is a huge potential and a need for the European Member States to learn from each other in the field of organ donation and transplantation.

A more elaborated working document, containing an action plan and the Quality and Safety Principles will be prepared for final consultation by 2nd quarter of 2008.

ANNEX: LIST OF PARTICIPANTS

Country	Surname	Name	
AUSTRIA	KURZ	Johann	Bundesministerium für Gesundheit, Familie und Jugend
AUSTRIA	MUEHLBACHER	Ferdinand	Medical University
BELGIUM	MUYLLE	Ludo	Federal Agency for Medecines
CZECH REP	POKORNA	Eva	IKEM
DENMARK	GRUNNET	Niels	Scandiatransplant
ESTONIA	DMITRIEV	Peeter	Tartu University Hospital
FINLAND	KATTELUS	Mervi	Ministry of Social Affairs and Health
FINLAND	HERMANSON	Terhi	Ministry of Social Affairs and Health
FRANCE	LIFFRAN	Geneviève	Ministère de la Santé
FRANCE	LOTY	Bernard	Agence de la biomedicine
GERMANY	KÜGELE	Stephan	Ministry of Social Affairs and Health
GERMANY	OGNYANOVA	Diana	Private expert
GERMANY	KIRSTE	Günter	DSO
GREECE	STAVROPOULOS	Catherine	Ministry of Health
HUNGARY	KÓBORI	László	Transzplantációs Klinika
ITALY	NANNI COSTA	Alessandro	Ministry of Health
LATVIA	DAUGAWANAGA	Anita	Health statistics and Medical Technologies Agency
LATVIA	ROZENTAL	Rafail	Latvian Transplantation Department
LUXEMBOURG	SCHARLL	Gérard	Direction de la Santé
MALTA	DELICATA	Nadine	Ministry of Health

NETHERLANDS	ELENBAAS	Marit	Ministry of Health
POLAND	CZERWIŃSKI	Jarosław	Poltransplant
PORTUGAL	AGUILAR	Maria João	Ministry of Health
PORTUGAL	RODRIGUEZ	João	Ministry of Health
ROMANIA	ZOTA	Victor	National Transplant Agency
SLOVAK REPUBLIIC	LACA	Ludovit	Ministry of Health
SLOVENIA	SOJAR	Valentin	University Medical Centre
SWEDEN	ERICZON	Bo-Göran	Karolinska Institutet
SWEDEN	ZETTERBERG-FERGREN	Petra	Ministry of Health
UK	NORMAN	Triona	Depatrment of Health - Human Tissues
UK	FALVEY	Sue	UK Transplant
EUROTRANSPLANT	OOSTERLEE	Arie	Eurotransplant
EUROTRANSPLANT	MEISER	Bruno	Eurotransplant
SCANDIATRANSPLANT	JAKOBSEN	Arnt	Scandiatransplant
EDQM (CoE)	BEHR-GROSS	Marie-Emmanuelle	European Directorate for the Quality of Medicines
DG SANCO	PIHA	Tapani	European Commission
DG SANCO	FERNANDEZ-ZINCKE	Eduardo	European Commission
DG SANCO	ZARDOYA	Maria	European Commission

ANNEX 1

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Brussels, 23 October 2007
SANCO C6

NATIONAL EXPERT MEETING ON
ORGAN DONATION AND TRANSPLANTATION AT COMMUNITY LEVEL:
WORKING GROUP ON QUALITY AND SAFETY

BRUSSELS 23 OCTOBER 2007
9:00 – 17:00

SUMMARY REPORT

The first meeting of the working group on quality and safety in organ donation and transplantation was held in Brussels on 23 October 2007 chaired by Tapani Piha. Fourteen countries, Eurotransplant and Scandiatransplant were represented by nineteen experts.[1]

1. WELCOME AND INTRODUCTORY REMARKS

Tapani Piha welcomed the participants to the meeting focusing on the follow up of the Commission Communication on Organ Donation and Transplantation.

The aim of this meeting was to exchange views between technical experts regarding the draft working paper on quality and safety framework on organ donation, procurement, testing, transport, preservation, transplantation and characterization of human organs.

[1] Member States represented: Belgium, France, Germany, Hungary, Ireland, Italy, Poland, Portugal, Slovenia, Spain, Sweden, UK, the Netherlands, representatives of Eurotransplant and Scandiatransplant.

ANNEX: List of Participants

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. FOLLOW UP TO THE COMMISSION COMMUNICATION ON ORGAN DONATION AND TRANSPLANTATION

The Portuguese Presidency has proposed draft conclusions to the Health Council, at the time of the meeting under discussion. If adopted, it would be the first time that the Council issues conclusions recognising the importance of organ donation and transplantation.

In the European Parliament MEP Adamos Adamou (CY, GUE-NGL) has been appointed rapporteur for the Communication with a provisional time table for the adoption of the EP opinion in April.

4. DISCUSSION ON THE WORKING PAPER

The working paper was presented and discussed section by section, giving the participants the opportunity to make detailed comments on each section of the document.

4.1. General provisions

General provisions includes the objective, scope, definitions and implementation by the Member States.

Most participants considered it appropriate to avoid giving the impression that the objective of the framework is to establish very stringent standards.

Regarding the scope of the provisions, many experts stated that the allocation should be discussed and in the definitions, while certain experts considered it should remain solely under national legislation. Clarification of the difference between allocation and distribution is needed.

A general concern was expressed regarding the definition of serious adverse event (SAE) and serious adverse reaction (SAR) even if the same definitions have been already used by the Council of Europe. Experts asked for a clearer definition of what it should be understood under both terms in order to avoid unnecessary reporting.

Further definitions should be incorporated, such as donation, domino transplantation, split transplantation, and establishment. Clarification on the definition of procurement would be desirable.

4.2. Obligations of Member State authorities

The chapter describes the main mechanisms that Member States should put in place.

The majority of the participants agreed that the directive should minimize the impact on donation centres and not to create extra work that could have a negative effect on organ donation rates. Hospitals should be stimulated to donate.

The authorisation should focus on the procurement conditions.

Some participants supported special authorization for transplantation centers but others considered that transplantation does not differ from other medical treatments and thus special authorization should not be requested.

Eurotransplant and Scandiatransplant mentioned their special concern about the authorization needed when importing organs from third countries. Norway, Iceland and Croatia, while not EU members, maintain regular organ exchange with EU countries. The Commission will check the legal mechanism with the Legal Service.

Many participants disagreed on the need of inspections but agreed on changing the term "inspection" to "audit" as part of a quality and safety process. Even if Article 152 specially mentions organ transplantation, some experts considered the activity to be equal to any other medical therapy. They underlined that inspection guidelines are not needed as this activity is under normal health care inspection in many Member States.

While recognising the interest of gathering information on transplantation activities and the value of a register of authorised centres, further discussion is needed on to what extend this should be covered in the legal text.

4.3. Donor protection

Most experts supported the measures proposed which aim at protecting donors and ensuring that the donation is made altruistically and voluntary. However some participants had questions on the legal basis.

There was a general agreement on consent, data protection and general principles governing organ donation, as well as on the need for a separate section on the protection of the living donor.

4.4. Provisions on the quality and safety

Some experts underlined that the quality system should be focused on the donation-procurement process. The importance of having a good donor identification and deferral system was underlined.

Some experts doubted the need to have a reference to national guidelines on risk assessment and allocation. Others expressed the need for a clearer definition of risk assessment and what an acceptable risk means for a donor.

The work by the Alliance-O project could serve as a basis for organ characterisation. The project will deliver to the group a simple and feasible donor data set.

4.5. Cooperation between MS

The chapter focuses on measures to promote cooperation in order to share experience and best practices and on how some of the measures are aiming to ensure the quality and safety and optimal use of organs in case of cross border organ exchange.

The need for cooperation in the field of organ donation and transplantation was acknowledged by the participants. Small countries in particular may need such cooperation.

Some experts said that the directive should support cooperation on organ exchange but there is no need to establish legal requirements. They suggested to transfer this provision to the action plan.

4.6. Committees and technical requirements

Some participants indicated that the definition of technical requirements through comitology should be limited to the minimum.

5. CONCLUSIONS AND NEXT STEPS

The chair concluded that there is a clear need for learning from each other in the field of organ donation and transplantation in the European Union, promoted by an action plan. The elements of a legal framework discussed in the meeting would support the mobility in the EU and ensure legal certainty. Much further work is needed to define better the scope of the legal framework and the details of its different elements. This legal framework should be seen in combination with the action plan.

The Commission will modify the working document, taking into account the comments and concerns of all participants for a further discussion by experts from all member stats.

6. Conclusion of the meeting/next steps

It was concluded at the meeting that there is a huge potential and a need for the European Member States to learn from each other in the field of organ donation and transplantation.

A more elaborated working document, containing an action plan and the Quality and Safety Principles will be prepared for final consultation by 2nd quarter of 2008.

ANNEX: LIST OF PARTICIPANTS

MUYLLE	Ludo	BELGIUM	AFMPS/FAGG
LIFFRAN	Genevieve	FRANCE	Ministére de la Santé
LOTY	Bernard	FRANCE	Agence de la Biomédecine
HEEMANN	Uwe	GERMANY	President of the German Transplantsociety Nephrology Klinikum rechts der Isar Munich
KIRSTE	Günther	GERMANY	Deutsche Stiftung Organtrasplantation
KÓBORI	László	HUNGARY	Semmelweiss Egyetem Transzplantációs és Sebészeti Klinika
ONEILL	Freda	IRELAND	HSE
NANNI COSTA	Alessandro	ITALY	Istituto Superiore di Sanità
CZERWIŃSKI	Jarosław	POLAND	Poltransplant
WALASZEWSKI	Janusz E.	POLAND	Poltransplant
AGUIAR	Maria João	PORTUGAL	Autoridade para os Serviços de Sangue e para a Transplantação
AVSEC-LETONJA	Danica	SLOVENIA	Slovenija-Transplant
DOMINGUEZ GIL	Beatriz	SPAIN	Organización Nacional de Trasplantes
ERICZON	Bo-Goran	SWEDEN	Karolinska Institutet
HAASE-	Bernadette	The Netherlands	Nederlanse Transplantatie Stichting

KROMWIJK			
NORMAN	Triona	UK	Depatrment of Health - Human Tissues
FALVEY	Sue	UK	UK Transplant
RAHMEL	Axel	Eurotransplant	Eurotransplant
JAKOBSEN	Arnt	Scandiatransplant	Scandiatransplant
PIHA	Tapan	DG SANCO	European Commission
FERNANDEZ-ZINCKE	Eduardo	DG SANCO	European Commission
BREGEON	Thomas	DG SANCO	European Commission
ZARDOYA	Maria	DG SANCO	European Commission