



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Directorate D – Health systems and products
D4 – Substances of human origin and Tobacco control

Brussels, 30 April 2012

FOURTH COMPETENT AUTHORITY
MEETING ON ORGAN DONATION AND TRANSPLANTATION

1 MARCH 2012, 13.30-18:00

2 MARCH 2012, 9:00-16.30

BRUSSELS

Place: CCAB room 1C

MINUTES

PARTICIPATION:

- All EU Member States were present except Luxembourg and Portugal.
- EEA countries: Norway present, absent: Iceland and Liechtenstein
- Candidate countries: Croatia, fYRoM, Montenegro, Turkey present
- Observers: Council of Europe present, WHO HQ excused, ECDC represented, as well as Commission/agency colleagues from Executive Agency for Health & Consumers (EAHC, project officer for SoHO field), DG SANCO D2 (for cross-border Directive and data protection issues) and DG JUST (from Data Protection Unit).
- Private experts: Eurotransplant, Scandiarttransplant and NIVEL (contractor for ACTOR study).

1. WELCOME AND INTRODUCTORY REMARKS

2. ADOPTION OF THE AGENDA

Because there is no speaker available, it is proposed to discuss agenda point 9.2.1 (transport regulation) in September 2012, if still relevant.

3. INTRODUCTION OF NEW PARTICIPANTS

4. TECHNICAL WORKING GROUPS (WGS) UNDER THE ACTION PLAN: QUICK UPDATES

4.1. Technical WG on deceased donation: update on the Manual on Transplant Coordinators (COMM)

Objective: as deceased donation was identified as a key area to increase organ availability (challenge 1 of the Action Plan, AP) this working group was the first activated in 2008 and 2009, with the objective to share knowledge and best practices. After discussions, the focus chosen was the promotion of "transplant donor coordinators" and how to set-up a system of donor coordination (priority action 1 of the AP).

Work done: A Manual was prepared by WG members in which several national experiences are shared (BE, FR, IT, PT, ES, SE, UK). The last physical meeting of the WG took place in December 2010, the Manual was finalised in June 2011 and translated over Summer in the languages requested by Member States (MS) (BG, DE, FR, NL, LV, RO, SK). The translations were (or are being) checked. Final versions are on CIRCA. Now it's up to MS to use the Manual (issue of publication was raised already during last CA meeting: no need, it is a technical Manual for Competent Authorities, not for general public).

Comments/questions: FR considers Manual as useful for French-speaking partners from Maghreb; EL considers the Manual as useful to reinvigorate the national system and asked if it would still be possible to get a translation. Although previous translations were done on 2011 budget, COMM will check and come back to EL.

4.2. Technical WG on Indicators: update after meeting on 9 February (COMM)

Objective: share common indicators to get a better picture and a common understanding of organ donation and transplantation at EU level, following 6 key areas (1. donation, 2. waiting lists, 3. allocation, 4. transplantation, 5. health outcomes, 6. health resources). The objective is to build a limited number of high-level indicators allowing every Member State to come to some learnings on strong points and learning opportunities.

Work done: A first exercise was run in 2010, a second in 2011. The Working Group has met on 9/2 and discussed the feedback of the 2011 exercise as it was presented to the CA meeting of September 2011. The 2011 exercise has been completed with data provided by 24 Member States. The WG meeting was the occasion to close the 2011 exercise and to take on board some comments for the 2012 exercise.

Use: The data indicates some areas for EU action, including optimal use of deceased donor organs, living donation, use of expanded donor criteria, use of cardiac death donors, cross-border exchange and possible agreements. Each MS is invited to look at it for its national use. Data and indicators still need significant improvement in quality. It was therefore agreed that the data and indicators are to be treated confidentially and cannot be disclosed (unless already public in the Council of Europe Newsletter).

Next steps: The 2012 exercise will be based on a simplified version of the 2011 exercise (less questions, for example on waiting lists and allocation criteria) but remain similar where possible in order to allow for a historical comparison over 3 years. Most quantitative data will be collected through ONT, while the Commission-run survey will collect additional qualitative and quantitative data. ONT data collection will happen as usual (Spring) and Commission web-survey should be online by May. **Member States will be asked to provide data by end June.** The aim is to have a good WG meeting end of early July with as much data as possible, for a fruitful presentation to CAs in September 2012.

4.3. Technical WG on Living donation: update after meeting on 10 February (COMM)

Objective: Build a common "toolbox" with references to expertise and experiences from Member States and from projects on how to set up a Living Donation Programme. Target audience is the national competent authorities in charge of setting up a living donation programme, therefore the scope for the toolbox is to support organisational systems, not to address medical questions.

Work done: A meeting of the working group took place on 10/2. The WG discussed a structure, addressing all elements to be tackled for setting up a living donation programme. Chapters will cover legal, ethical, donor selection, donor registries, psychological, financial/economic and organisational. For each chapter a member of the WG will draft a short section summarizing key points of attention and including links to sources/documents with relevant links

Next steps: COMM and WG called for inputs/reference documents to include in the exercise. These can be provided to COMM and/or the leaders of the chapters by 15th of April. Drafts of the chapters will be prepared for the next meeting in July.

5. SET OF NATIONAL PRIORITY ACTIONS

5.1. Presentation of Set of National Priority Actions

5.1.1. Ireland

IE presented national actions. IE has a bilateral agreement with UK for organs which can not be allocated in IE and for urgent needs.

5.1.2. Turkey

TR presented the national actions as well as its legislation on composite tissue transplants, which raised a high interest within the CA group, as other countries are

reflecting on this (AT, BE, CZ, FR, DE, UK). TR historically has many living donations and is currently increasing efforts for cadaveric donations. TR agreed to transmit an English version of this legislation for a circulation within the group.

5.1.3. Scandiatransplant contribution

SKT presented its set of actions and its contribution to national actions of SKT countries. About 20% of organs are exchanged cross national borders between the SKT countries, which leads to increased health outcome/survival, in particular for highly immunized patients.

5.2. Discussion and exchange of views on Set of National Priority Actions

The above MS presented their National Priority Actions; these National Action Plans (NAPs) are a reflection of the 10 priority actions of the EC Action Plan. These presentations will be used also by the contractor NIVEL for the ACTOR study, see following point.

Member States interested to present their national priority actions during the next meeting are invited to express their interest (to be confirmed prior to next meeting in Sept. 2012).

6. MID TERM REVIEW OF THE ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION (2009-2015)

6.1. Introduction: objectives and frame (COMM)

COMM prepared a general & introductive presentation on the Action Plan and the ACTOR study foreseen as a basis to the Mid Term review of the Action Plan (tender, process, 4 Work packages, kick-off meeting (19 January), audio-meeting (February), data to be collected as much as possible in advance by contractor, based also on 2009 survey...).

Key message concerning this review: this is an exercise from and for Competent Authorities, to learn in comparison of what others do, or on what they have done over time. Therefore a high participation is expected, in the own interest of CAs. COMM insisted on the confidentiality agreement with NIVEL and the fact that data collection will be organised to avoid heavy burden for CAs.

The study will provide a basis for adoption of conclusions by the Council meeting of Health Ministers in December, under the Cypriot Presidency. There is a lot of political support within CY for organ donation, and some conclusions can be adopted by the group of Ministers. This is an occasion to get political attention for the work on organ donation and transplantation. This means that COMM will have the opportunity to pre-discuss with CY authorities on potential key messages before Summer. COMM already asked the CA group for possible key issues for Council Conclusions, and the following topics were mentioned:

- self-sufficiency is to be seen at EU level (not only national) and therefore there is a high potential in more cross-border collaboration and exchange of organs and patients.

- living donation (donor with emotional relationship, need for donor follow-up, avoid discrimination of donors (insurance)...))
- public awareness building, communication with families,
- consent systems (opt-in/opt-out),
- need for sufficient funding for donation and transplantation activities, cost-effectiveness of transplantation,
- need to evaluate impact of ageing, availability and use of older donors, older recipients (extended criteria donors).

NIVEL and COMM would present the draft ACTOR report and possible ideas of Council conclusions to the next CA meeting on 13-14/9. Then COMM would work on drafting in the Council Working Group in the course of October to ensure a document for adoption by November.

6.2. Presentation of the process and of the contractor (NIVEL)

NIVEL presented the team, the process and the methodologies chosen for the ACTOR study (first desk research, then confirmed/completed by national contacts). This study is a tool for CAs: to get recommendations at EU but also national levels.

6.3. Discussion and exchange of views with participants

Some questions were asked on the methods and on the timeline foreseen for the ACTOR and answered by NIVEL.

NIVEL asked for volunteers to check the survey which will be afterwards proposed to the whole group. NL, SI, TR, ES (tbc) and NO proposed to do so.

7. PRESENTATION OF NATIONAL COMPETENT AUTHORITIES

7.1. Presentation of some national set-up of Competent Authorities

7.1.1. Slovakia

SK presented the activities for which the CAs is the oversight organisation. Financing issues were raised.

7.1.2. Slovenia

SI presented the CA activities.

7.1.3. Greece

EL presented the new national legislation which enabled to completely reinvigorate the transplant activities, as well as how it obtained support from the Greek orthodox Church. First results are positive, with doubled donation rates..

7.2. Discussion and exchange of views on national set-up

All MS are currently in the process of setting up or reshaping their national competent authority, in order to comply with art 17 of Directive 2010/53/EC by August 2012.

HU volunteered to present their national CA set-up during the next meeting. Further CAs are invited to present their set-up.

8. INTERNATIONAL ACTIVITIES

8.1. Update on enlargement process

COMM presented a short overview table on the enlargement process.

8.2. Discussion and exchange of views on international activities

9. CROSS-BORDER EXCHANGES

9.1. Update on the Implementing Measures

COMM provided a short update on what was discussed and decided in the Committee on 1 March. Discussions were not finalised and a second meeting of the Committee will be organised in April.

9.2. Cross-border exchange of organs and patients: update on other Community legislation

9.2.1. Update on the Transports regulation EG/300/2008

This point will be moved to the next meeting, if relevant.

9.2.2. Update on the Cross-Border Directive for patients mobility

COMM (SANCO D2) presented the Cross-Border Healthcare Directive to be transposed by Member States for 2013.

9.3. Update on the Data Protection legislation

COMM (DG Justice, Data Protection Unit) presented the new proposal on Data Protection.

10. EUROPEAN PROJECTS FUNDED UNDER THE PUBLIC HEALTH PROGRAMME

10.1. Projects

10.1.1. COORENOR (IT)

An update was made on the developments within the COORENOR project.

Developments within the ODEQUS and ELIPSY projects could be presented during the next CA meeting.

10.2. Joint Actions

10.2.1. 2010 Joint action MODE (IT)

An update was made on the developments within the MODE Joint Action.

10.2.2. 2012 Joint action (COMM/IT)

COMM and CNT (IT) introduced the Joint Action (JA) and different work packages, calling for interest of the other Member States. The 2012 JA will focus on cross-border collaboration and it is important for Member States to step in, in particular for those (smaller or new) Member States who have not all transplant programmes developed within their borders: such agreements can provide for a cost-efficient access to transplant programmes and for an optimal utilisation of organs.

10.2.3. 2011 Joint Action ACCORD (ONT)

ONT presented the objectives and work packages foreseen under the 2011 JA ACCORD. The Kick-off meeting will probably take place early June in Madrid.

10.3. Tender

10.3.1. TX coordinators: "Training the Trainers" (ONT)

This tender launched in 2010 financed for 2 face-to-face sessions (in Sept. and Nov. 2011) in addition to the e-learning phases for 80 participants of all Europe, mainly national or regional transplant coordinators with training responsibilities. CAs were asked to nominate possible participants from their countries.

ONT presented the implementation and results of the course. COMM highlighted the very professional organisation by consortium ONT and IAVANTE. COMM is very interested in the "post-assignment" reports of participants. **CAs were asked to appoint participants as "multipliers" to train colleagues at national and regional level.**

CAs (NL) asked Commission to implement a short survey within the CA group concerning the course and their intention to "use" the national participants sent to the course. This survey is attached, **please fill it out and send it back to helene.leborgne@ec.europa.eu by 15 June.**

10.4. Next Public Health Programme 2014-2020

10.4.1. Update on the process and topics

The SoHO project officer in the Executive Agency for Health & Consumers (EAHC) presented some elements available on the next Programme.

A general discussion with the group followed the presentation of the various projects funded under the Public Health Programmes and CAs (AT) asked to get more visibility on how to access deliverables and presentations on ongoing and past projects (DOPKI, Alliance-O). COMM reminded that many documents were already uploaded in the CIRCA platform and it was agreed to circulate the list of links to the different relevant websites.

Useful links to websites and webpages relevant for European activities and projects on Organ donation and transplantation:

- **EAHC - projects database** for projects funded under the Health Programme:
<http://ec.europa.eu/eahc/projects/database.html>

(example, for ETPOD <http://ec.europa.eu/eahc/projects/database.html?prjno=2005205>)

- **CIRCA** (for internal use of the **CA group for Organs**: various sub-sections under "Library", presentations made during CA meetings, WG meetings...)

- **European Commission – DG SANCO** (policy, Journalists Workshops on Organ donation and transplantation):
http://ec.europa.eu/health/blood_tissues_organs/organs/index_en.htm

(example for Journalists Workshops:

*http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm
*htm)**

- **Health EU portal**: http://ec.europa.eu/health-eu/index_en.htm

11. REPORT ABOUT LAST JOURNALISTS WORKSHOP ON ORGAN DONATION AND TRANSPLANTATION, 18 OCTOBER 2011, BRUSSELS

COMM prepared a short summary of the last Workshops (and articles published) and also passed the word also to national representatives who took part.

Some CAs expressed their interest in organising similar events at national. Presentations made during the last Workshop are available on CIRCA and **CAs are asked to provide names of national journalists potentially interested in the 2012 European Workshop**. Further patient testimonies (and possibly from families of deceased donors) should be done. Social media are also of growing interest.

It was agreed also to propose a slot during the next CA meeting for CAs to present their national communication strategies on organ donation and transplantation. **CAs are invited to express interest in presenting their national communication plans in September.**

12. ECONOMICS OF ORGAN TRANSPLANTATION: EXCHANGE OF DATA AND DISCUSSION

COMM prepared a presentation with data from FR, ES, UK.

Several countries have published some data on the cost-efficiency of organ transplants. Outcomes of these studies show that in particular kidney transplants are cost-efficient compared to dialyses and create significant annual savings, while adding quality of life for the patients.

However, the set-up of an organ transplant programme requires an upfront investment, which might not be evident in times of economic scrutiny. The CAs therefore want to gather different data and analyses that Member States have developed, so that they are also at the disposal of the other Member States.

CAs are invited to send additional data to COMM for sharing with the whole group.

13. ANY OTHER BUSINESS

14. CONCLUSION OF THE MEETING

Next CA meeting is planned for 13-14 September.

Dominik SCHNICHELS