European activities in the field of Organ donation and transplantation

Journalist Workshop on Organ donation and transplantation
7 October 2013

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Substances of human origin ("SoHO")

3 sectors explicitly mentioned in the Treaty as «SoHO»:

- Blood and blood derivatives
- Tissues and cells
- Organs
  - kidneys
  - livers
  - hearts
  - lungs
  - pancreas
  - small bowel
## EUROPEAN UNION DATA

<table>
<thead>
<tr>
<th>Organ Transplant Type</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney Transplants</td>
<td>18,854</td>
<td>21.0% (LD)</td>
</tr>
<tr>
<td>Liver Transplants</td>
<td>6,845</td>
<td>3.6% (LD)</td>
</tr>
<tr>
<td>Heart Transplants</td>
<td>1,960</td>
<td></td>
</tr>
<tr>
<td>Lung Transplants</td>
<td>1,756</td>
<td></td>
</tr>
<tr>
<td>Pancreas Transplants</td>
<td>825</td>
<td></td>
</tr>
<tr>
<td>Small Bowel Transplants</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>Patients Transplanted</td>
<td>30,274</td>
<td></td>
</tr>
</tbody>
</table>

### 9637 ACTUAL DECEASED ORGAN DONORS (both DBD and DCD included)

*2012 data

N = 27 COUNTRIES (503.1 million inhabitants)
Deceased organ donors - 2012

In terms of deceased donation:
Best practices in the south of Europe

Source: Council of Europe / ONT 2013 Transplant Newsletter
In terms of living donation:

Best practices in the north of Europe + Cyprus, Turkey

Source: Council of Europe / ONT 2013 Transplant Newsletter
Liver transplants – 2012

Source: Council of Europe / ONT 2013 Transplant Newsletter

Some countries more specialised in certain types of transplants
Not all countries have all types of transplant programmes.

- **Bilateral or multilateral agreements** between countries can be useful:
  - to exchange organs
  - to treat patients
  - also better chances for a good « match » between donor organ and recipient
  - to support building own capacities (twinning)

Eurotransplant (8 countries), Scandiatransplant (5) and South Alliance for Transplant (3) are European Organ Exchange Organisations.
Article 168 of the Treaty on the Functioning of the European Union: “setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives”

  - Adopted on 7 July 2010
  - To be transposed by into national laws by 27 August 2012
  - Establish/consolidate « National Competent Authorities » (NCAs) in charge of the quality and safety framework
  - NCAs meet twice a year in Brussels, participate in EU-funded projects...

- Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation
  - Aligns communications on organ characterisation (offering), traceability and alerts
  - Adopted on 9 October 2012
  - To be transposed by into national laws until 9 April 2014
• Chain from donation to transplantation, from donor to recipient

3 levels:

1. Procurement/transplant centres
   - Selection, consent...

2. National Competent Authorities
   - HIV, Hepatitis B, Hepatitis C...
   - Oversight: vigilance, traceability, accreditation, inspection...

3. European Commission
   - Processing Quality requirements
   - Support tools: traceability, rapid alert system system...
• The following areas are **outside of the scope of the Directive**:  

  - Consent systems (opt-in / opt-out)  
  - Waiting lists  
  - Allocation criteria  
  - Legislation around brain death  
  - Health systems and resources  

→ The areas remain **national competence**  

→ However, the Commission can encourage Member States to **share experiences through collaboration under the Action Plan** (voluntary tool)
• **International cooperation** (Council of Europe, WHO)

• Activities under the **Action Plan on organ donation and transplantation (2009-2015)** (a Communication from the Commission adopted in December 2008) – 3 main objectives:
  → increase organ availability
  → improve transplant systems (efficiency and accessibility)
  → improve quality and safety

• **Tools** at disposal under the Action Plan:
  → **Projects** funded under the **EU Health Programme**
  → **Working groups**:
    → deceased donation (Manual on how to set a system of transplant donor coordination)
    → indicators
    → living donation
  → **Journalists Workshops**
Organ donation and transplantation: policy actions at EU level

10 PRIORITY ACTIONS (2009-2015)

1. Improve quality and safety
2. Make transplantation systems more efficient and accessible
3. Increasing organ availability

EU LEGAL FRAMEWORK = Directive

= Action Plan

**OBJECTIVES**

1. Increase Organ Availability
   - 1 transplant coordinators
   - 2 quality improvement programmes
   - 3 living donation programmes
   - 4 communication skills of professionals
   - 5 information on citizens rights

2. Enhance Efficiency and Accessibility of Transplantation Systems
   - 6 enhance organisational models
   - 7 EU-wide agreements
   - 8 interchange of organs

3. Quality and Safety
   - 9 evaluation of post-transplant results
   - 10 common accreditation system

**10 PRIORITY ACTIONS**

Halfway 2009-2015: Mid-term review of the Action Plan

- Council Conclusions adopted on 7 December 2012 by EU Health Ministers
- Study on the uptake of the action plan, financed by the Commission under the EU Health Programme (ACTOR study)

Examples of projects funded under EU Health Programme


- **Project:** “Train the trainers in transplant donor coordination” (2011)
  - for national/regional/local trainers (80 participants from all Europe)
  - to increase organ availability

- **Joint action ACCORD – Assisting Member States in reaching the full potential of deceased and living donation** (2012-2015)
  - Collaboration between transplant coordinators and intensive care units
  - Registers for living donors
  - Twinning programmes

- **Project to support cross-border exchanges: FOEDUS – Facilitating exchange of organs donated in EU Member States** (2013-2016)
  - further develop an IT tool to offer organs cross-border
  - encourage cross-border agreements to facilitate organ exchanges
  - agree on communication strategies

Also: COORENOR, EDD, EULID, ELIPSY, EFRETOS, ODEQUS... projects
See in the press pack: “useful links”

Also **Research projects** funded under the Framework Programmes (FP6, FP7): DOPKI, Alliance-O, RISET, HepaMab, The ONE study, COPE...
Objective: increase public awareness of organ donation (offering different views, facts & figures, testimonies...)

Linked to EU Action Plan (PA 4) and organised ahead of European Organ Donation Days (EODD) co-organised by Council of Europe and hosting country (Belgium in 2013, Hungary in 2012...) [http://eodd2013.be/](http://eodd2013.be/)

Participation: totally 113 journalists from 28 countries

→ articles/press releases/videos after the 3 first editions published on our website (and translated)

→ and articles submitted under the EU Health Prize for Journalists [http://ec.europa.eu/health-eu/journalist_prize/](http://ec.europa.eu/health-eu/journalist_prize/)

Articles from the previous Workshops on our website: [http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm#fragment1](http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm#fragment1)

→ Please send us your articles after publication
Today's different views

Flow

Donor → Organs → Recipient

Process

Donation/Collection → Test → Allocate → Transport → Human application

Actors

Donor/Procurement center: Luc (coordinator), Axel (Eurotransplant), Jacques (transplant surgeon)

Delegated bodies: Rafael (Spain), Thomas (Germany)

Transplant Center

Oversight

National Competent Authority (NCA)

Support

European Commission, SoHO team

Policy: http://ec.europa.eu/health/blood_tissues_organs/organs/

Documents:
- Programme
- List of participants
- Useful links (national contact points, international organisations & EU projects)
- Facts & figures
- Link to 2013 Transplant Newsletter (CoE/ONT)
- Eurobarometer 2009-10
- Link to 2013 European Organ Donation Day in Belgium
- Satisfaction survey (please fill in and give back before leaving today)

Presentations will be published.

Also in the press pack:
- Directives, Action Plan, Council conclusions
Our team for "Substances of human origin" (SoHO)


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THANK YOU!