European activities in the field of Organ donation and transplantation

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Directorate General for Health & Consumers - European Commission
1) European landscape

- Organ donation → deceased donation
- Organ donation → living donation
- Organ donation → donation over time
- Transplantation

2) EU action

- EU legislation
- EU Action Plan
- EU-funded projects

3) Communicating about organ donation & transplantation
Thanks to Eurobarometers, we also know that European citizens are in favour of donating their organs after death (EU average: 55% say "yes, I would be willing to donate organs immediately after my death")

Eurobarometer 333a, October 2009

See also Eurobarometers 183.5 (Dec. 2002) and 272.d (Nov. 2006)

Also in your press pack!

high deceased donation rates in Europe

Sources: 2014 Transplant Newsletter (Council of Europe/ONT)
Highest rates of deceased donation (> 30 pmp) in the South of Europe

Source: 2014 Transplant Newsletter (Council of Europe / ONT)
1) European landscape
Living donation (2013)

Highest rates of living donation in the North of Europe + Turkey, Malta

Also in your press pack!

Source: 2014 Transplant Newsletter
(Council of Europe / ONT)
Constant increase in the EU in the last 10 years, thanks to living donation

Source: annual Transplant Newsletters 2005 to 2014 (Council of Europe / ONT)
1) European landscape
Donation & Transplants

Total 31,165 patients transplanted in the EU in 2013 (62% kidney tx)
9912 deceased donors and 4,450 living donors in 2013
A constant increase since 2004

**EUROPEAN UNION DATA**

<table>
<thead>
<tr>
<th></th>
<th>Transplantations</th>
<th>Donations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney Transplants</td>
<td>19,227 (21.8% LD)</td>
<td>7,123 (3.6% LD)</td>
</tr>
<tr>
<td>Liver Transplants</td>
<td>7,123 (3.6% LD)</td>
<td></td>
</tr>
<tr>
<td>Heart Transplants</td>
<td>2,037</td>
<td></td>
</tr>
<tr>
<td>Lung Transplants</td>
<td>1,825</td>
<td></td>
</tr>
<tr>
<td>Pancreas Transplants</td>
<td>865</td>
<td></td>
</tr>
<tr>
<td>Small Bowel Transplants</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Patients Transplanted</td>
<td>31,165</td>
<td></td>
</tr>
</tbody>
</table>

2013 data

*2013 data
N= 28 COUNTRIES (508,7 million inhabitants)

Also in your press pack!

Organs transplanted in the European Union
(for the ease of comparison, all 28 EU Member States in 2014 are included for all the years considered, independently on when they joined the EU. Ex: Croatian figures included also prior to 2013)

Source: 2014 Transplant Newsletter (Council of Europe / ONT)
1) European landscape

Transplants: Europe in the world

European activities compared to global activity in organ transplantation

Source: 2013 and 2014 Transplant Newsletters, Global Observatory on Donation & Transplantation

<table>
<thead>
<tr>
<th>2012 transplants</th>
<th>Kidney</th>
<th>Liver</th>
<th>Heart</th>
<th>Lung</th>
<th>Pancreas</th>
<th>Small bowel</th>
<th>Organs transplanted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global activity</td>
<td>77818</td>
<td>23986</td>
<td>5935</td>
<td>4359</td>
<td>2423</td>
<td>169</td>
<td>114690</td>
</tr>
<tr>
<td>(% living donation)</td>
<td>(42.3%)</td>
<td>(18.2%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EU (with Croatia)</td>
<td>19085</td>
<td>6973</td>
<td>2004</td>
<td>1756</td>
<td>833</td>
<td>34</td>
<td>30685</td>
</tr>
<tr>
<td>(% living donation)</td>
<td>(20.8%)</td>
<td>(3.7%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of global activity</td>
<td>24.5%</td>
<td>29.1%</td>
<td>33.8%</td>
<td>40.3%</td>
<td>34.4%</td>
<td>20.1%</td>
<td>26.8%</td>
</tr>
</tbody>
</table>

For EU + Turkey, Norway, Iceland: 32 % due to high living donation rates in Turkey

→ more than 25 % of transplants worldwide took place in the European Union in 2012 (one third for EU + Turkey, Norway, Iceland)

→ the rate of kidney transplants from living donors worldwide (42%) is twice higher than the rate for the European Union (21%)

→ for EU + Turkey, Norway, Iceland: 32 % due to high living donation rates in Turkey
Heart transplants rates lower than kidney or liver transplant rates
Some countries have no heart transplant programmes → high added value of cooperation/agreements with other countries, to propose solutions to their patients

Source: 2014 Transplant Newsletter
Some countries have **no** lung transplant programmes

Different countries have developed **different kinds of expertise**

→ **high added value of cooperation/agreements with other countries**

Source: 2014 Transplant Newsletter
Many countries are members of "European Organ Exchange Organisations" (EOEOs)
- Eurotransplant: 8 EU Member States (Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, Slovenia)
- Scandiatransplant: 3 EU Member States (Denmark, Finland, Sweden) + Iceland and Norway
- South Alliance for Transplant: Now 5 partner countries: 4 EU Member States (France, Italy, Portugal, Spain) plus Switzerland and 1 observer: Czech Republic

Many EU Member States have **bilateral agreements and/or fixed collaborations** with neighbouring countries, for example:
- Spain - Portugal
- Italy - Malta
- Ireland - United Kingdom
- etc.
2) Action at the level of the European Union (EU)

- EU legislation:

  (a Communication from the Commission)

- EU-funded projects
  - Research projects (see press pack)
  - Public Health projects
Legal basis: 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”

2) EU Action
Legal basis for "substances of human origin" (SoHO)

3 sectors explicitly mentioned in the Treaty:

→ Blood and blood derivatives

→ Tissues and cells

→ Organs

Cover (even if not explicitly listed):
- kidneys
- livers
- hearts
- lungs
- pancreas
- small bowel
- vascularised composite allografts

- Adopted on 7 July 2010
- To be transposed by into national laws by 27 August 2012
- EU network of National Competent Authorities meet and exchange twice a year
- Currently:
  - "transposition check" to verify if Directive correctly transposed
  - "implementing survey" to understand how the Directive is implemented in EU Member States

**Commission Implementing Directive** 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

2) EU Action Directive: key elements for quality and safety

3 levels:

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

2. National Competent Authorities
   - Oversight: vigilance, traceability, authorisation, inspection...

3. European Commission
   - Support tools: traceability, rapid alert system system...

Donation  | Collection  | Testing  | Preserve  | Prepare  | Transport  | Distribute  | Transplantation
---|---|---|---|---|---|---|---

Support tools: traceability, rapid alert system system…
2) EU Action
Scope, key principles

- **Quality and safety of organs** (chapter II, Articles 4 to 12)
  - Framework for quality and safety
  - Procurement and procurement organisations
  - Organ and donor characterisation
  - Reporting system, management of serious adverse events & reactions
  - Healthcare personnel

- **Donor and recipient protection, donor selection and evaluation** (III)
  - Principles: voluntary and unpaid donation
  - Consent requirements
  - Quality and safety of living donation, protection of living donors
  - Protection of personal data, confidentiality and security of processing

- **Obligations of competent authorities, exchange of information** (IV)
  - Designations and tasks of CAs (authorisation, control/audit etc.)

- **Organ exchange with third countries and European Organ Exchange Organisations** (V)

- **General provisions** (VI): reports, penalties, transposition etc.
The following areas are **outside of the scope of the Directive:**

- Consent systems (opt-in / opt-out)
- Management of waiting lists
- Allocation criteria
- Ethical aspects, legislation around brain death
  - But internationally: **medical** consensus on when & how to determine brain death
- Health systems and resources
  - Including decision to start/stop specific donation/transplantation programmes

→ The areas remain **national competence**

→ However, the Commission can encourage Member States to **share experiences through collaboration under the Action Plan** (voluntary tool)
with the **World Health Organisation** (WHO)
- Mutual information
- Ethical issues (non commercialisation etc.)
- Declaration of Istanbul on Organ Trafficking and Transplant Tourism

WHO Guiding principles on transplantation (11):
1: « Organs may be removed from the bodies of deceased persons for the purpose of transplantation if (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal »
2: « physicians determining that a potential donor has died should not be directly involved in organ removal from the donor or subsequent transplantation... »
3: « Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients. » Other principles (no donation by living minor except narrow exceptions allowed under national law, no payment, allocation to be guided by clinical criteria and ethical norms etc.)

with the **Council of Europe** (47 members, including EU Member States): for consistent transplant policies at European level
- Guide on the quality and safety of organs → for healthcare professionals at hospital level (transplant coordinators for ex.)
- Resolutions on transplant donor coordinators, living donation etc.
- **Convention against Trafficking in Human Organs** (July 2014): complementary to EU legislation against trafficking in human beings (including for the purpose of organ removal)

**1. Improve quality and safety**

**2. Make transplantation systems more efficient and accessible**

**3. Increasing organ availability**

**EU LEGAL FRAMEWORK**

- Directive (July 2010)

**10 PRIORITY ACTIONS (2009-2015)**

- Action Plan (Dec. 2008)
2) EU Action
The Action Plan

OBJECTIVES

Increase Organ Availability

Enhance Efficiency and Accessibility of Transplantation Systems

Quality and Safety

10 PRIORITY ACTIONS

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

6 enhance organisational models
7 EU-wide agreements
8 interchange of organs

9 evaluation of post-transplant results
10 common accreditation system

Working groups
- Deceased donation
- Living donation
- Indicators

2012-2013: mid-term review
- Council Conclusions (dec. 2012)
- ACTOR study
- Commission’s document

2016: final evaluation
Research projects: on organ preservation, immuno-suppression, xenotransplantation etc.

Public health projects:

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

Joint Action FOEDUS – Facilitating the Exchange of Organ Donated in EU Member States (2013-2016), to support cross-border exchanges
- develop an IT tool to offer cross-border organs which cannot be used at national level
- identify barriers to organ exchanges and encourage cross-border agreements to facilitate organ exchanges
- agree on communication strategies

More information in your press pack!
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

3) Communicating about organ donation and transplantation

Communication: an important element for increasing organ availability

« organise regular meetings with journalists »

- National days,
- European Organ Donation Days (2nd Saturday in October, Council of Europe + hosting country)
- Journalist Workshops
Communication - a topic for several EU-funded projects:
- Train the trainers in transplant donor coordination (train coordinators)
- European Donation Days (toolkit for event organisers)
  http://www.europeandonationday.org/
- FOEDUS (support Competent authorities developing their communication capacities: optimise initiatives to improve public awareness)

European Organ Donation Days: Council of Europe event, each year hosted in a different country (hosted in Belgium in 2012, in Italy in 2013, Portugal in 2014)
  http://www.eodd2014.it/eodd-2014-eng/

Personal stories / celebrities
- famous persons in the country (donor, transplanted patient, opinion leaders, including religious leaders)
- human stories (not necessarily famous persons)
At the occasion of the 2014 European Organ Donation Day in Rome (Italy), the Pope Francis made a declaration in favor of organ donation at the end of the Holy celebration: donation of organs after death is "a distinctive witness of love for others" and "abuses and trafficking (of organs) should be avoided" (8 Oct. 2014) http://w2.vatican.va/content/francesco/it/audiences/2014/documents/papa-francesco_20141008_udienza-generale.html (in Italian only)

Already on 19 September 2014, Representatives from the (WHO) Declaration of Istanbul Custodian Group (DICG) had an audience with the Pope Francis, who declared: “Organ trafficking and commercialization are immoral - DICG is at liberty to convey this message on my behalf”

President of Turkish Religious Affairs (Mehmet Görmez, 2013) at the conference which held by the Ministry of Health and the Turkish Transplant Foundation “all religions totally support the donation, there is no difference between Christian and Muslim world about this issue. Giving life to a person means giving life the whole humanity”.
Objective: increase public awareness

Participation: totally 150 journalists from 30 countries, specialised & general media

In press pack: also national contact points

→ When shared with us by authors, articles/press releases/videos published on our website (and translated) after all editions

http://ec.europa.eu/health/blood_tissues_organs/events/journalist_workshops_organ_en.htm#fragment0
3) Communicating about organ donation
Today’s different views

Flow
Donor → Organs → Recipient

Process
Donation/Collection

Test → Allocate → Transport

Human application

Actors
Donor/Procurement center
- Luc coordinator
- Axel (Germany)

Delegated bodies
- Juliëtte (Eurotransplant)
- Regina, Emily

Transplant Center
- Jacques transplant surgeon

Oversight
National Competent Authority (NCA)

Support
European Commission
- Rafael (Spain)
- SoHO team
- You media

SoHO team

Health and Consumers

You media

**Martin Seychell**
**Andrzej Rys**
**Dominik Schnichels**

And...

**Team « Substance of human origin » (SoHO):**

**Helene Le Borgne**  
**Richard McGeehan**  
**Stefaan Van der Spiegel**  
**Ioana Siska**  
**Paolo Catalani**  
**Alina Cornea**  
**Monica Gheorghe and Andrea Haller**

Deputy Director-General for Health  
Director Health systems and products  
Head of Unit, SoHO & Tobacco control

Policy officer, organs  
Legal officer, organs, tissues&cells  
Team-leader SoHO  
Policy officer, tissues&cells  
SoHO, support  
SoHO, support  
Trainees

**THANK YOU FOR YOUR ATTENTION !**