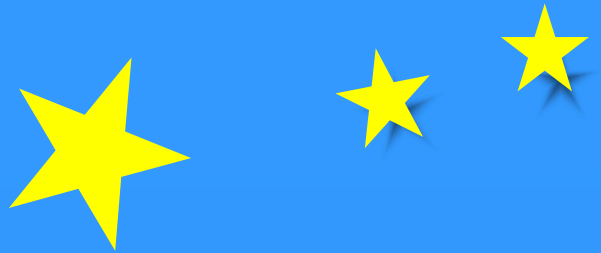


Council of Europe actions and activities in organ donation.

*Per PFEFFER, MD, PhD
Ljubljana, October 2008*





COUNCIL OF EUROPE

Background

Founded in 1949

Currently 47 Member States

Headquarters: Strasbourg, France

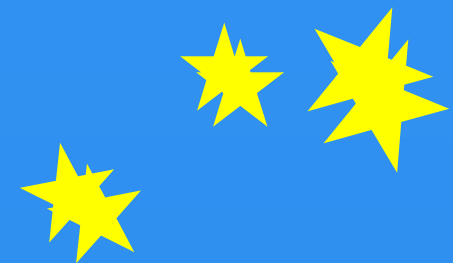
Principles:

Human rights

Democracy

Rule of law

Social cohesion





THE ROLE OF THE CoE IN THE AREA OF ORGAN TRANSPLANTATION

- Harmonisation of legislation and policies amongst the countries
- Ethical aspects
 - ✓ Non-commercialisation of substances of human origin
 - ✓ Protection of donors and recipients
- Technical aspects
 - ✓ Quality
 - ✓ Safety
 - ✓ Organisation





WORKING METHODS

Committee of Ministers

- **Steering Committees** *(answerable to the Committee of Ministers)*

- European Health Committee (CDSP)
- Steering Committee on Bioethics (CDBI)
- European Committee on organ transplantation (CD-P-TO)





ACTIVITIES

- ✓ 1) Policy / organisation
- ✓ 2) Standard setting
 - ✓ 3) Monitoring
 - ✓ 4) Field action
- ✓ Including international cooperation (EU, WHO)





Early steps in the field of transplantation

- **Resolution (78) 29** (Committee of Ministers 11 May 1978)

On harmonization of legislation of member States relating to removal, grafting and transplantation of human substances.





1) POLICY / ORGANISATION

- **Conventions/Agreements (binding)**
- **Recommendations/Resolutions (non binding)**
 - **Consensus reports**





- Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997)

The aim of the Convention is to protect human dignity and integrity, as well as rights and fundamental freedoms, in the face of scientific and medical advances.

Transplantation is concerned essentially in the field of protection of living donors






The Oviedo Convention defines « Prohibition of financial gain of a part of the human body » (chapter VII)

The explanatory report to the Convention specifies in point 132 « Under this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital »...

Further, this Article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income (for example as a result of hospitalisation).



Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin *(ETS 186)*.

Open for signature on 24 January 2002, in Strasbourg

Develop and complement the principles of the Convention in the field of organ transplantation

Objective: to ensure protection of donors and recipients

General provisions:

Transplantation system

Professional standards

Information for the recipient

Health and safety:

Medical follow-up (**living donors and recipients**)

Information for health professionals and the public



Additional Protocol (*ETS 186*).

- **Groups of principles underlying the provisions:**
 - Obtaining organs
 - Allocating organs
 - Good technical and medical practices
- **Provisions designed to encourage donation while guaranteeing a high level of protection for the fundamental rights of both the donors and the recipients**



Additional Protocol (ETS 186) – Obtaining organs

◆ Scope of protection of living donors (Articles 9 and 10)

- ◆ Organ removal from living donor only if :
 - therapeutic benefit for the recipient
 - absence of suitable organ available from a deceased donor
 - no alternative **therapeutic** method of comparable effectiveness

- ◆ Close personal relationship between the donor and the recipient, otherwise approval by an independent body

- ◆ Restrictions on removal from donors without capacity to consent (**Article 14**)
 - only regenerative tissue
 - brother or sister of the recipient
 - donation must have the potential to be life saving for the recipient



Additional Protocol (ETS 186) – Good technical and medical practices

- ◆ **Transplantation system**
 - ◆ Obligation on the States to guarantee the existence of a transplantation system (Article 3)
 - ◆ Professional involved in transplantation to take measures to minimise risks regarding health and safety (Article 6)



Additional Protocol (ETS 186) – Good technical and medical practices

- ◆ **Information, consent and confidentiality**
 - ◆ Free, informed and specific consent for living donor in writing or before an official body (Article 13)
 - ◆ For living donors: Prior appropriate information required on purpose, nature, consequences and risks of the removal (Article 12)
 - ◆ For recipients: Prior appropriate information required on purpose, nature, consequences and risks of the transplantation as alternatives to intervention (Article 5)
 - ◆ Confidentiality of personal data (Article 23)

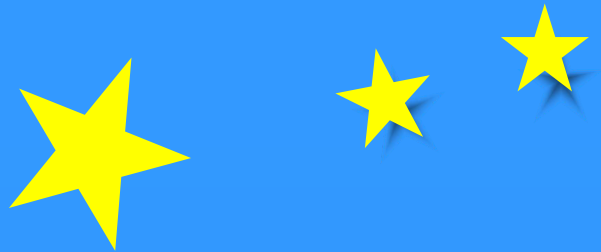
- ◆ **Appropriate medical follow up required for both living donors and recipients (Article 7)**



Additional Protocol (ETS 186) – Allocating organs

◆ Criteria: Fairness and transparency (Article 3)

- ◆ Solely to patients registered on an official waiting list
- ◆ Governing rules: transparent, objective and duly justified according to medical criteria
- ◆ *Remark: Important also for building public confidence in the transplantation system*



Convention on Action against Trafficking in Human Beings Warsaw, 16 May 2005 (CETS 189)

1st February 2008: Entered into force

Trafficking of human beings for the purpose of removal of organs also falls under the scope of this convention

<http://www.coe.int/t/DG2/TRAFFICKING/campaign/>





Recent Recommendations

- **Recommendation Rec(2006)15 of the Committee of Ministers to member states**
 - on the background, functions and responsibilities of a National Transplant Organisation (NTO)
- **Recommendation Rec(2006)16 of the Committee of Ministers to member states**
 - on quality improvement programmes for organ donation
- **Recommendations recently adopted (March 2008):**
 - ✓ Non-related live kidney donation
 - ✓ Living donor liver transplantation



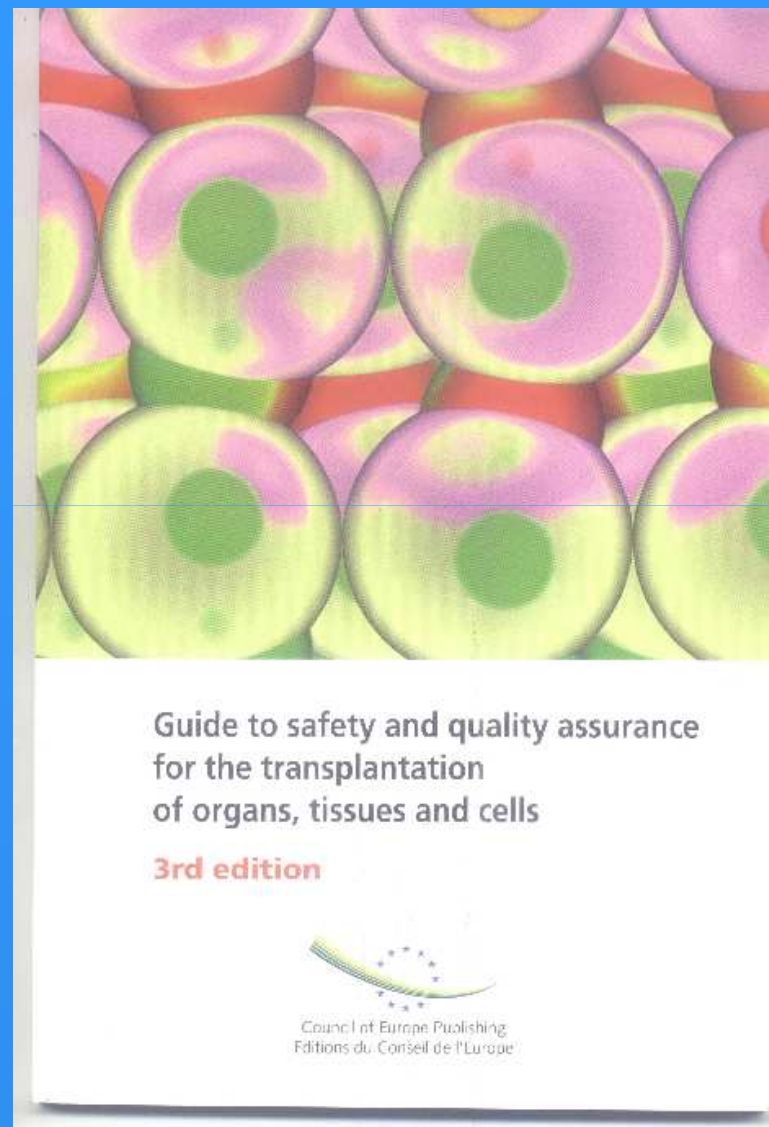


★ 2) STANDARD SETTING

Guide to
safety and
quality
assurance for
organs,
tissues and
cells

3rd edition
2006

4th revision
coming soon...





3) MONITORING

Transplant NEWSLETTER:
annual organ donation
rates in Council of Europe
Member States





4) FIELD ACTIONS

✓ Assistance Activities:

Experts sent on the field to advise governments on ethical principles, quality, and organisation

Recent examples:

- Romania, Ukraine
- Georgia, Moldova

✓ Conferences, Donation Day





EUROPEAN DAY ON ORGAN DONATION AND TRANSPLANTATION

1996 : Switzerland

1998 : Austria

2000 : Cyprus

2002 : Portugal

2003 : Greece

2004 : Sweden

2005 : Switzerland with 1st World Organ Donation Day

2006: Istanbul

2007: Dublin

2008: Ljubljana





5) International Cooperation

- **with the EU:** EC Public Health Directorate in the area of quality and safety of organs and substances of human origin
 - EU 2004/23 Directive on Tissues and Cells.
 - Future Organ Transplantation directive
- **WHO:** Global Consultation





CONCLUSIONS

Importance of Inter-Governmental institutions to promote and support ethical standards in Organ Transplantation...and of governments to support international consensus on ethical principles

Regional recommendations, based on widely recognised ethical values and scientific knowledge, can open the way for international consensus



CONCLUSIONS

Ethical respect makes nations stronger and provides common universally accepted standards that should promote donation and public trust of which these activities are so dependent.



Thank you

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(EDQM secretariat)
for their contribution to this presentation







Current CD-P-TO Agenda

- ✓ **Current Issues:**
 - ✓ Criteria on neoplastic disease screening
 - ✓ National Donor Registers
 - ✓ Non-heart-beating donors: survey
 - ✓ Islet isolation and transplantation
 - ✓ Revision of the guide on safety and quality

- ✓ **Items for future consideration:**
 - ✓ Draft booklet on living transplantations
 - ✓ **Transplantation for non-residents and migration issues : survey**
 - ✓ **Organ trafficking and tourism: joint survey under preparation United Nations/Co of Europe**
 - ✓ International organ exchange: survey
 - ✓ Liver cell transplantation: state of the art

