

Report on the legislation regarding donation and transplantation of organs from living donors in eleven european countries

WORKING GROUP 1

This report is designed to illustrate the state of the art of legislative and regulatory approaches in the field of living donation (LD) and transplantation of organs, among eleven EULID project partner European Countries.

In order to fulfill the task of analyzing legislations and bylaws in these Countries, we searched national and international publications dealing with legal and ethical concerns in the field of living donation and transplantation of organs. Also we made a survey in the partner Countries by creating a very detailed survey questionnaire (see in Annex 1) addressing all the issues on this area we considered noteworthy:

- The general legislative and regulatory layout in the field of living donation and transplantation, including the sanctions and penalties applied in case of major violations (i.e. procurement in persons without obtaining consent, or in persons unable to consent, organ trafficking, organ sale or purchase, and transplant tourism);
- The legislated or regulated enactments on donor-recipient relationship, including paired/pooled donation and unrelated directed and non directed donation;
- The legislated or regulated procedures on the organizational aspects of living donation: the evaluation of the donor, the information for the donor and the consent of the donor, and the provisions surrounding the post-donation follow-up and the protection of the living donors, including the existing LD follow-up registries;
- The existing legislations and regulations on financial, economical and social concerns regarding the living organ donor.

The report of this survey is supported by the answers given by Cyprus, France, Italy, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden and the United Kingdom (UK) to the questionnaire sent in MS-Word format to members of Working Group 1 of the EULID Project.

I. GENERAL ASPECTS OF LIVING DONATION AND LIVING DONOR TRANSPLANTATION

Provisions with regard to living donation and transplantation have been developed in Countries and also at a supranational level primarily in order to protect the potential donor, and also to prevent the threatening problem of organ trafficking. They imply more or less severe limitations in the living donor procurement and transplantation activities, which are consequently regulated by law in all participating countries.

I.1. International legislation and recommendations

I.1.1. World Health Organization

The World Health organization (WHO), the United Nations specialized agency for health, has adopted in the World Health Assembly in 1991 the **Guiding Principles for human organ transplants (Resolution WHA 40.13)** which have had a great influence on professional codes and legislations. These principles emphasized voluntary donation, non-commercialization, and the preference for deceased donors over living donors and for genetically related donors over non-related donors. On 22 May 2004, the 57th World Health Assembly adopted the **Resolution WHA 57.18 concerning human organ and tissue transplantation**, recommending notably the extension of the use of living donors, in addition to deceased donors, and to take measures to protect the poorest and vulnerable groups from “transplant tourism” and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs.

I.1.2. The Council of Europe

In Europe, an important source of rules concerning the issue of living organ donation and transplantation are the documents of the Council of Europe (COE):

- **The Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology: Convention on Human Rights and Biomedicine** (Oviedo Convention) was adopted on April 4th 1997 and came into force on December 1st 1999 (CETS No.:164). It is the first legally-binding supranational text designed to preserve human rights and dignity from the misappropriate use of medical advances. Specific provisions of this convention apply notably to the procurement of organs from living persons, the prohibition of financial gain, and sanctions.

In the chart below are shown the status on May 2008 of the dates of signature, ratification and entry in force of the Convention in the different EULID participating Countries.

States	Date of signature	Date of ratification	Entry into force
Cyprus	30/09/1998	20/03/2002	01/07/2002
France	03/04/1997		
Italy	03/04/1997	28/03/2001	24/04/2001
Norway	03/04/1997	13/10/2006	01/02/2007

Poland	07/05/1999		
Portugal	03/04/1997	13/08/2001	01/08/2001
Romania	03/04/1997	24/04/2001	01/08/2001
Slovenia	03/04/1997	05/11/1998	01/12/1999
Spain	03/04/1997	01/09/1999	01/01/2000
Sweden	03/04/1997		
United Kingdom			

- **The Additional Protocol to the Convention for the protection of Human Rights and Biomedicine** was adopted in Strasburg on January 24th 2002, and came into force on May 1st 2006. It applies the principles of the Oviedo Convention of Human rights an Biomedicine to the field of organ transplantation, covering all concerns on living donation:

Article 7 - Medical follow-up Appropriate medical follow-up shall be offered to living donors and recipients after transplantation.

Article 11 - Evaluation of risks for the donor Before organ or tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor. The removal may not be carried out if there is a serious risk to the life or health of the donor.

Article 12 - Information for the donor The donor and, where appropriate, the person or body providing authorisation according to Article 14, paragraph 2, of this Protocol, shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular, they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.

Article 13 - Consent of the living donor Subject to Articles 14 and 15 of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body. The person concerned may freely withdraw consent at any time.

In partner countries on May 2008, the Additional Protocol is signed by Italy, Portugal, Slovenia and Spain, and it is ratified and entered in force only in Slovenia.

- Since 1994, **the committee of ministers of the COE released a series of recommendations and resolutions** regarding the issues of organ donation and transplantation of human organs, including questions addressing to living donation and transplantation. While not having a binding effect, these recommendations and resolutions have also a great influence on regulations and legislation in European Countries:

■ [Resolution CM/Res\(2008\)6](#) of the Committee of Ministers to member states on transplantation of kidneys from living donors who are not genetically related to the recipient.

■ [Recommendation Rec\(2006\)16](#) of the Committee of Ministers to member states on quality improvement programmes for organ donation.

■ [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\(2004\)19](#) of the Committee of Ministers to member states on criteria for the authorisation of organ transplantation facilities.

■ [Recommendation Rec\(2004\)7](#) of the Committee of Ministers to member states on organ trafficking.

■ [Recommendation Rec\(2003\)12](#) of the Committee of Ministers to member states on organ donor registers.

■ [Recommendation No R\(97\)16](#) of the Committee of Ministers to member states on liver transplantation from living related donors.

- **The Council of Europe Convention on Action against Trafficking in Human Beings (CETS N° 197)** was adopted by the Committee of Ministers on 3 May 2005 and opened for signature in Warsaw on 16 May 2005, on the occasion of the 3rd Summit of Heads of State and Government of the Council of Europe.

- The Convention is a comprehensive treaty mainly focused on the protection of victims of trafficking and the safeguard of their rights. It also aims at preventing trafficking as well as prosecuting traffickers.
- The Convention applies to all forms of trafficking; whether national or transnational, whether or not related to organized crime. It applies whoever the victim: women, men or children and whatever the form of exploitation: sexual exploitation, forced labor or services, slavery or practices similar to slavery or the **removal of organs**;

I.1.3. The European Union

Finally at the level of European Union (EU), **the Article 152 of the Amsterdam Treaty requires that the European Parliament and the Council** adopt measures setting high standards of quality and safety of organs of human origin, and that these measures must not prevent any Member State from maintaining or introducing more stringent protective measures; the same Article states that the Community shall encourage cooperation between the Member States in the areas referred to in that Article and, if necessary, lend support to their action.

- The European Commission adopted [a Communication](#) on 30 May 2007 on “**Organ donation and transplantation: Policy actions at EU level**” (COM(2007 275 final). As an annex to the Communication the Commission provided a comprehensive [impact assessment](#), which

identifies the major policy challenges in respect to organ donation and transplantation, including living donor activities.

This Commission Communication on organ donation and transplantation intends to respond to these challenges based on the mandate in Article 152(4)(a) of the Treaty, which enables the European Parliament and Council to adopt harmonised health measures on the basis of the co-decision procedure pursuant to Article 251 EC, by setting high standards of quality and safety of human organs. It sets out the actions the Commission is planning to take to respond to the main policy challenges in relation to organ donation and transplantation: ensure quality and safety of organs, enhancing the efficiency and accessibility of transplantation systems in the EU Member States and increase organ availability and fight organ trafficking.

The communication entails two mechanisms of action: an action plan for strengthened coordination between Member States and an EU legal instrument on quality and safety of organ donation and transplantation. The action plan will be based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting, and identification and exchange of best practices. The envisioned EU legal instrument will complement the cooperation approach taken under the action plan by providing an appropriate and flexible European legal framework.

- On May 2008, European Parliament has adopted **the European Parliament [Resolution 2007/2210 on organ donation and transplantation: Policy actions at EU level](#)**, in response to the Commission Communication on the subject. Several of the provisions included in this resolution have an impact on living organ donation and transplantation:

*Concerned with guaranteeing the **quality and safety of organ donation** and transplantation, Parliament await a **proposal for a Directive** from the Commission establishing the quality and safety requirements for the donation, procurement, verification, preservation, transport and distribution of organs in the European Union and anticipating the resources to fulfill these requirements. However, they emphasize that the future legal framework must not place additional administrative responsibility on Member States or on service providers; challenge the use of existing good practice, or include requirements which would lead to a lower number of potential and actual donors.*

*Expressing their concern regarding the **scarcity of human organs** available for transplantation, Members of the European Parliament await an **action plan** from the Commission aiming to strengthen cooperation between Member States in order to: (i) increase organ availability; (ii) strengthen the efficiency and accessibility of transplantation systems; (iii) increase public awareness; and (iv) guarantee quality and safety. Parliament underlines that the establishment of well-structured operational systems in the Member States or between them is extremely important.*

*- With regard to **increasing the availability of organs**, Parliament stresses the importance of financing organ procurement and transplantation under a dedicated budget line, so as not to make transplantation a disincentive for hospitals. Members go on to underline the need to ensure that **organ donations stay strictly non-commercial**. Any payments between donors and recipients must be confined solely to compensation strictly limited to making good the expense associated with the donation. Member States must adopt strict legal provisions, in order to exclude the possibility of illicit organ selling or coercion of donors. Parliament also urges Member States to ensure that living donors are not discriminated against, in particular by insurance systems.*

- With regard to improving the **efficiency and accessibility of transplantation systems**, Parliament notes that, although several Member States have introduced compulsory registration of transplant activities, there is no comprehensive system for the collection of data on the different types of transplantation and their outcomes. It strongly recommends the creation of national follow-up registers of living donors, transplanted patients and transplant procedures, and stresses the importance of ensuring the comparability of the data between Member States.

- Parliament highlight that **organ trafficking** undermines the credibility of the system for potential voluntary and unpaid donors. In order to combat the practice of organ selling for money (especially in countries of the developing world), mechanisms of traceability should be put in place so as to prevent those organs from entering the EU. The Commission and Member States are called to take measures to prevent 'transplant tourism', notably by enacting guidelines which aim to protect the poorest and most vulnerable donors from becoming victims of organ trafficking, and by adopting measures to increase the availability of legally procured organs. Those responsible for organ trafficking must be subject to prosecution, including sanctions for medical staff involved in transplantation of organs obtained from trafficking.

I.2. Inventory of existing national parliamentary acts and binding and non binding regulations in participating Countries

In all the eleven EULID participating Countries, living organ donation and living donor transplantation are regulated by parliamentary acts (see chart below).

Country	Parliamentary acts on living organ donation and transplantation	Binding and nonbinding regulations on living organ donation and transplantation below national parliamentary acts
Cyprus	- Law of 1987 (L. 97/87). Removal and Transplantation of Biological Substances of Human Origin.	-This Act contains provisions addressing the approval of institutions carrying out living donor procurement and transplantation, the safeguard of life and health of organ living donors, and the registration of the donor consent under a written form
France	- Revised Bioethics Law 2004, covering the fields of organs, tissues, cells; (Laws 94-653 and 94-654, July 29 th , 1994 ; law 2004-800, August 6 th , 2004 ; Public Health Code, second book, first part; Penal Code including sanctions for illegal living donor activities such as selling or purchasing organs)	- The law is detailed by several decrees in each field, particularly in the field of living donation decrees regulating expert committees for living donors. - There are also ministerial orders (texts which are under decrees as legislative value) and circular letters (written instructions) detailing on how to apply the legal framework.
Italy	- Law 26.06.1967 n.458 "Kidney transplantation between living persons" - Law No. 91 of 1 April 1999 on the removal and transplantation of organs and tissues. <i>(Original text published in Gazzetta Ufficiale della Repubblica Italiana, 15 April 1999, No. 87)</i> Repeals Law No. 644 of 2 December 1975, as amended - Law No. 483 of 16 December 1999 promulgating rules on consent to partial liver transplantation. <i>(Ragiusan (Rassegna Giuridica della Sanità), March-April 2000, Nos. 190-191, p. 255. Original text published in Gazzetta Ufficiale della Repubblica, 20 December 1999, No. 297)</i>	- National Guidelines for transplant from kidney living donor issued by the Italian National Transplant Centre
Norway	- Law No. 6 of 9 February 1973 on transplantation, hospital autopsies, and the donation of cadavers, etc. - Law No. 31 of 8 June 2001 amending Law No. 6 of 9 February 1973 on transplantation, hospital autopsies, and the donation of cadavers, etc. <i>(Norsk Lovtidend, Part I, 4 July 2001, No. 7 pp. 818-819)</i> . Amendments to the principal Law (see IDHL, 1974, 25, 417) concern the following matters, inter alia: the prohibition of the commercial use of human organs, cells, and tissues (new Chapter IIIA (Secs. 10a-10b)).	- The law requires the living donor to give written informed consent before living donation. Other aspects regarding living donation are covered by codes of practices or guidelines
Poland	- The Cell, Tissue And Organ Recovery, Storage and Transplantation Act of July 1 st , 2005 <i>(the Official Journal of Acts Dziennik Ustaw 2005, no 169, pos. 1411)</i> 1) This Act changes the Police Act, of 6 April, 1990 and the Public Financing of Health Services Act, of 27 August, 2004.2) This Act implements the Directive 2004/23/EC of The European Parliament and The Council of The European Union of 31 March 2004 on setting standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (Official Journal of the EU L 102 of 7.4.2004).	- Act of the Minister of Health in issue of the Centre for Transplant Organization and Coordination, "Poltransplant", 28 th June 2006. <i>(Dziennik Urzędowy Ministerstwa Zdrowia 06.09.39)</i> - Decree of the Minister of Health in issue of cells, tissues and organs donor candidate requirements, 25 th April 2006. <i>(Dziennik Urzędowy Ministerstwa Zdrowia 06.79.556)</i> - Decree of the Minister of Health in issue of kind and range of living organ donors examinations performed within the confines of health monitoring, 25 th April 2006. <i>(Dziennik</i>

		<p><i>Urzędowy Ministerstwa Zdrowia 06.83.579)</i></p> <p>- Decree of the Minister of Health in issue of National Council of Transplantation status establishment, 5th May 2006. (<i>Dziennik Urzędowy Ministerstwa Zdrowia 06.84.584</i>)</p> <p>- Decree of the Minister of Health in issue of detailed conditions of cells, tissues and organs recovery, storage and transplantation, 16th July 2007. (<i>Dziennik Urzędowy Ministerstwa Zdrowia 07.138.973</i>)</p>
Portugal	<p>- Law No. 12/93 of 22 April 1993 on the removal and transplantation of human organs and tissues</p> <p>- Law No. 22/2007 of 29 June 2007 partially transposing into national law Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004, and amending Law 12/93 of 22 April 1993 on the removal and transplantation of human organs and tissues. (<i>Diário da República, Part I, 29 June 2007, No. 124, pp. 4186-4150</i>)</p>	<p>- Order No. 31/2002 of 8 January 2002 prescribing that the activity of the collection of tissues and organs of human origin for the purposes of transplantation and the activity of transplantation are to be subject to prior authorization by the Minister of Health after consulting the Portuguese Transplant Organization (OPT), and repealing Order No. 1245/93 of 6 December 1993. (<i>Diário da República, Part I-B, 8 January 2002, No. 6, pp. 150-152</i>)</p> <p>- Regulatory Decree No. 67/2007 of 29 May 2007 approving the organizational structure of the Authority for Blood and Transplantation Services. (<i>Diário da República, Part I, 29 May 2007, No. 103, pp. 3506-3509</i>)</p>
Romania	<p>- Law No. 39 of 21 January 2003 on preventing and combating organized crime (see <i>ibid.</i>, 2002, 53, Rom. 02.006) provides for the imposition of a prison sentence of from three to seven years for organizing or carrying out the removal or transplantation of human tissues or organs for profit-making purposes. The purchase of human tissues or organs for resale for profit-making purposes is subject to the same penal sanctions. Attempts are also punishable</p> <p>- Law no. 95/2006 concerning the reform in the health field - Title VI - "Performing of harvesting and the transplant of organs, tissues and cells of human origin with a therapeutic purpose" Official Journal, Part I no. 372 – 28 April 2006.</p>	<p>- Minister's of Public Health Order no. 1076 of 05 September 2006 for the approval of the Rules of organization and functioning of the Commission for the Approval of the Donation from living donor" Official Journal, Part I no. 763 - 07/09/2006</p> <p>- Minister's of Public Health Order no. 1597 of 11 December 2006 for the nomination of the members of the Commissions for the Approval of the donation from living donor. Official Journal, Part I no. 9 - 08/01/2007</p>
Slovenia	<p>- Law of 27 January 2000 on the removal and transplantation of human body parts for therapeutic purposes (ZOPDCT). (<i>Uradni list Republike Slovenije, 11 February 2000, No. 12, p. 1569 et seq., Text No. 560</i>). Comprises the following Chapters: I. General provisions (Secs. 1-6) (Sec. 4 prohibits the giving or receiving of financial reward or any other compensation for the removal of human body parts, without prejudice to the settlement of medical and technical expenses incurred by removal or transplantation); II. Removal of body parts from living donors (Secs. 7-11); IV. Administrative provisions (Secs. 19-22); V. Penal provisions (Sec. 23); and VI. Transitional and final provisions (Secs. 24-27) (the Minister responsible for Health is required to adopt implementing texts and to establish a transplantation ethics committee).</p>	<p>The provisions of the following texts are to apply, provided that they are compatible with the present Law: the Regulations on the conditions governing the removal and transplantation of human body parts, and the Regulations on the medical criteria and modalities for the determination of the death of persons from whom body parts may be removed for transplantation for therapeutic purposes^b (Sec. 24).</p>

Spain	<p>- Law 30-1979 of 27 October on procurement and transplantation of organs</p>	<p>- Royal Decree 2070/1999 + Annexes 1) certification of death 2) transplant centres</p> <p>- Royal Decree No. 176/2004 of 30 January 2004 approving the Statutes of the National Centre for Transplants and Regenerative Medicine. (<i>Boletín Oficial del Estado</i>, 31 January 2004, No. 27, pp. 4165-4171)</p> <p>- Royal Decree No. 1301/2006 of 10 November 2006 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells and approving the coordinating and operating standards for their use in humans. (<i>Boletín Oficial del Estado</i>, 11 November 2006, No. 270, pp. 39475-39502)</p>
Sweden	<p>-Transplantation law 2006 SFS (Svensk författningssamling) 2006:35. www.riksdagen.se</p> <p>-The Law 2006:354 makes provisions on punishment if there is trade with biological material.</p> <p>- The law 2003: 464 make provision that ethical approval is mandatory if research is made on humans.</p> <p>- The law 2004: 40 tells us that organs can not be removed from minor (below 18 years) persons with psychiatric disease not able to give a consent.</p>	<p>Aspects regarding living donation are covered by codes of practices or guidelines, not by law</p>
United Kingdom	<p>- The Human Tissue Act 2004: An Act (Chapter 30 of 2004) to make provision with respect to activities involving human tissues; to make provision about the transfer of human remains from museum collections; and for connected purposes. Dated 15 November 2004. (The Human Tissue Act 2004). An Act of the Scottish Parliament (asp 4 of 2006) to make provision in relation to activities involving human tissue. Date of assent: 16 March 2006. (The Human Tissue (Scotland) Act 2006).</p>	<p>- The United Kingdom Transplant Support Service Authority (Establishment and Constitution) Amendment Order 2000. S.I. 2000/1621. Dated 17 June 2000</p> <p>- The NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005. S.I. 2005/2529. Dated 9 September 2005.</p> <p>- The Human Tissue Act 2004 (Powers of Entry and Search: Supply of Information) Regulations 2006. S.I. 2006/538. Dated 1 March 2006</p> <p>- The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. S.I. 2006/1260. Dated 25 April 2006</p> <p>- The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants).) Regulations 2006. S.I. 2006/1659. Dated 22 June 2006</p> <p>- Other aspects are covered by Codes of Practice or Guidelines not by law.</p>

Specific national regulations with regard to living donation are included in legislation on organ and tissue transplantation in most of partner Countries. In France they are embodied in the legislation on Bioethical issues in Medicine.

It is of importance to note that due to the fact of the great differences on legal frameworks, culture values and geographical, historical and sociological backgrounds of the different countries involved, even if all countries have developed specific parliamentary acts addressing living donation concerns, it is found a huge heterogeneity between legislative contents. Some partner Countries, i.e. Sweden, Norway and Cyprus have developed only a minimal set of legal dispositions, while contrastingly in other Countries such in France, hard legislation (i.e. parliamentary acts) encompass all detailed provisions addressing to the LD procurement and donation activities, which are in other Countries considered in regulations or such in Scandinavian Countries, in guidelines or codes of practice. The consequence of this heterogeneity is that each procedure and concern on LD activities may be regulated, according to the Country, by the law, by binding or not binding regulations elaborated by the health authority or the national transplant authority, or by guidelines and codes of practice elaborated by professionals.

I.3. Procedure of authorization for living donation and transplantation activities

In ten Countries, the activities of LD procurement and transplantation are legally submitted to an authorization given by health authority to the transplantation centers, usually the national transplant authority. The only exception is Norway, country in which for historical and geographical rationales there is only one transplantation team within the country and not having set a national transplant Authority.

In the majority of Countries requiring administrative approval for LD activities (seven on 10 Countries), the authorization is specifically given for LD activities (procurement and/or transplantation), while in Portugal and Slovenia the authorization includes both cadaver and living donor procurement activities. In Cyprus, donation should be performed in an approved medical institution.

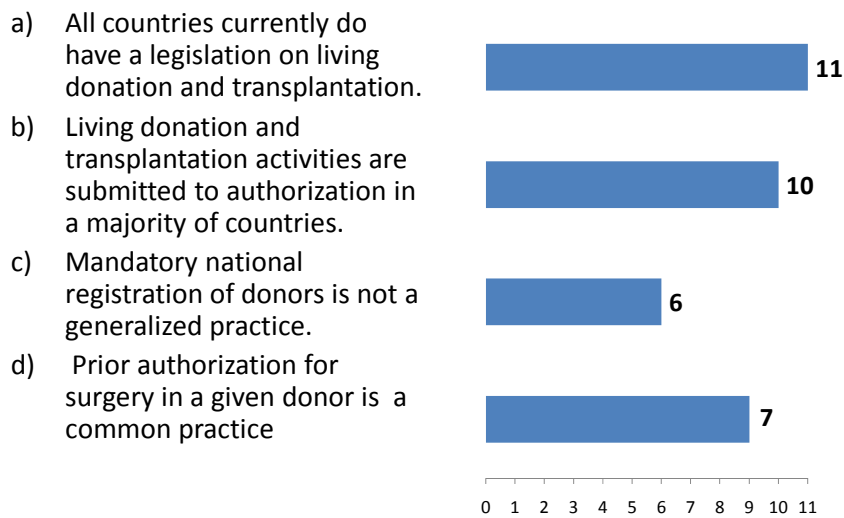
I.4. Procedure of prior approval for living donation surgery in a given donor

In Slovenia, Cyprus Norway and Spain it is not required to get an administrative approval before performing surgery in a given living donor. In Portugal, Italy, Romania and France the authorization should be requested by the transplant team and given by an ad hoc committee (in France the approval is not required if the donor is the father or the mother of the recipient). In Sweden, Poland and United Kingdom the transplant Authority gives the authorization. In Italy a magistrate is also involved in this procedure.

I.5. Registration of the donor prior to living donation surgery

Prior registration of living donors at national or regional level to the national transplantation authority is required by legislation or regulations in six countries. Registration is recorded at the level of the transplant team hospital in Portugal and Cyprus. In Sweden, Norway and UK, there is no mandatory registration of the donors.

Figure 1: General legislative and regulatory dispositions on LD procurement and transplantation activities



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I.6. Non-resident donor policies

Non-resident donors (from European and/or non-European Countries) are authorized to donate in all partner Countries, excepted in Cyprus. In Italy, Slovenia and Norway procurement of organs in living non-residents is possible only if the recipient is resident.

I.7. Living donor committees / commissions (Localization, dependence, members and role)

All countries except Cyprus have committees (commissions) involved in the process of donation. In Sweden, Norway, Poland, Portugal, Spain and Romania the committee is established at the hospital level. In Italy, Slovenia, UK and France it is set up at the regional or the national level.

The living donor commission may function as an independent and dedicated structure or as in Spain, Poland, Slovenia, and Portugal the commission is included in a generic committee (e.g. ethical committee). The commission is generally dependent from the transplant authority or from the Ministry of health, but in Italy it is independent and in Spain it is depending from the hospital/university.

As illustrated in the table below, the attributions of the committees are markedly different between participating Countries. In the large majority of countries (in eight Countries on ten), the main duty assigned to the committee is to give an authorization for donation. Also a large majority of commissions does have the task to evaluate the donor-recipient relationship (7 countries), as well the evaluation of donor suitability (6 Countries). Only a minority of committees plays a role in the information for the donors (5 Countries), directly or by verifying the content and the understanding of information given by the transplant physician.

Role of the committees	France	Italy	Norway	Poland	Portugal	Romania	Slovenia	Spain	Sweden	UK
Information for the donor										*
Evaluation of donor suitability										
Authorization for donation										
Donor-recipient relationship evaluation										

* In the UK, the information for the donor, as well the evaluation of donor suitability, are duties of the advocate of the donor (independent assessor), which operates under the authority of the human tissue authority (HTA) committee for living donors

According to their different attributions, the composition of the committees is also very heterogeneous between the participating Countries, as illustrated in the table below:

	France	Italy	Norway	Poland	Portugal	Romania	Slovenia	Spain	Sweden	UK
Transplant physicians										
Other physicians										
Advocate of the donor										
Psychologists/ Psychiatrists										
Nurses										
Ethicists										
Social workers										
Jurists/Lawyers										
Administrative staff										

A large majority of commissions includes in their members psychologists or psychiatrists (8 countries), as well they also include most often ethicists (8 countries). In seven countries the commission includes physicians, who are transplant physicians in 4 countries. The presence of a transplant team representative physician is allowed only in Norway and UK. In addition, commissions may include jurists (in 3 countries), administrative staff (in 3 countries), social workers (in Norway Slovenia and Spain), and nurses in Spain.

Of note, **an advocate of the donor** is required by most professional recommendations and by the resolution CM/Res(2008)6 of the Council of Europe. The advocate of the donor is defined

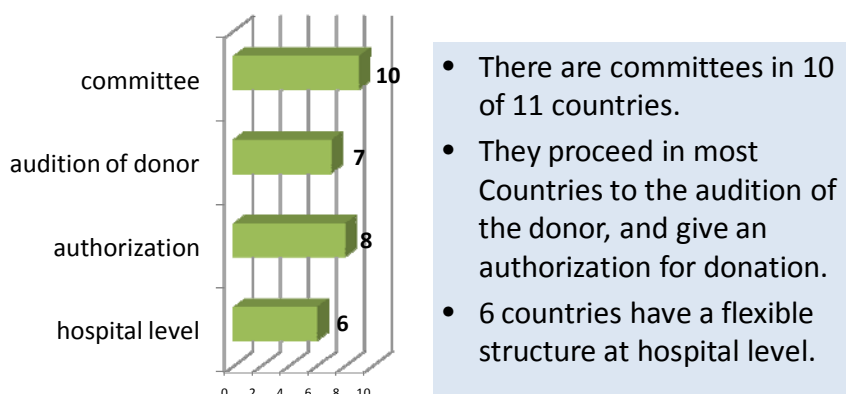
as “a professional having appropriate experience and who is not involved in the organ removal or subsequent transplantation procedure”. Such advocate of the donor only incorporated in the commissions of 2 Countries: UK and Poland. In the UK, the advocate is entitled “independent assessor”, is specifically trained, and operates at the level of the hospital transplantation center under the authority of the human tissue authority (HTA) committee for living donors. Its role, defined in the procedure guidance, is to assess potential donors, by way of an interview, to ascertain if the requirements of the law (Human Tissue Act) have been met. He must then complete and submit a report to the Authority, detailing whether the requirements have been met, and provide a recommendation regarding the donation (that is, whether the donation should be approved or not approved by the Authority). In Spain, the independent physician who is responsible to deliver information for the donors may be also considered as having some tasks attributed to the advocate of the donor.

Direct audition of the donor by the living donor committee is performed in all partner countries except in Slovenia and in UK, where this task is committed to the independent assessor. The audition is facultative in Spain, requested by the committee if necessary.

In case of refusal of the authorization by the committee, an appeal procedure is allowed in Norway, Poland and in UK. Other countries do not make provision of an appeal procedure.

The chart below summarize the main regulations on the living donor committees in participating countries

Legal and regulatory dispositions on donation procedure



I.8. Sanctions and penalties in case of violation of ethical and legal dispositions regarding living donation and transplantation

The **Convention on Human Rights and Biomedicine, and the Additional Protocol to the Convention on Transplantation of Organs and Tissues of Human Origin** stipulate that “*parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in the Convention and the Protocol:*

- *The prohibition of financial gain or comparable advantage from the human body and its parts, and the prohibition of advertising the need for, or availability of organs or tissues, with the view to offering or seeking financial gain or comparable advantage.*
- *The prohibition of organ and tissue trafficking.*
- *The prohibition of organ removal on a person who does not have the capacity to consent, including minors and persons who have a mental disorder. An organ may be removed from a living donor only after the person concerned has given free, informed and specific consent to it in written form or before an official body. The person concerned may freely withdraw consent at any time”.*

The **Convention on Action against Trafficking in Human Beings** contains also important provisions addressing to the criminalization of trafficking in human being, the criminalization of the use of services of a victim, and effective, proportionate and dissuasive sanctions and measures in case of criminal offences that shall be adopted by each Party.

Organ commercialism and organ trafficking are submitted to penal prosecutions and sanctions in all EULID partner Countries, with exceptions in Cyprus, and Spain. In Spain transplantation law does not prescribe any sanctions, but refer to the penal code which does not consider such cases specifically. Transplant tourism is only specifically considered in the Penal code of France.

The procurement of organs in persons unable to consent, including minors and mentally-disabled is condemned and submitted to penal sanctions in most of partner Countries. In Cyprus, Italy and Poland however, the procurement in minors and/or mentally disabled is not referred, in contradiction to the Convention on Human Rights and Biomedicine signed by all participating Countries, except the UK.

II. DONOR-RECIPIENT RELATIONSHIP DEFINITION

The definition of the relationship between the organ donor and its recipient may be of importance, with regards to ethical, legal and also medical concerns surrounding living organ donation and transplantation. According to the degree of relation between donor and recipients, different categories of living donations should be distinguished:

- The transplantation of an organ from a living donor to a **genetically related** recipient, which is worldwide a well established practice for decades in the case of living donor

kidney transplantation. The donor may be brother or sister, father or mother, child, grand parent, cousin of the 1st degree or cousin of further degrees of the recipient.

- The transplantation of an organ from a living donor to a **non-genetically, related** recipient. Another proposed terminology for such donors is “emotionally-related donors”. The donor may be a spouse, a legally-registered or a non-registered partner or a friend of the recipient. This category comprises also the legally-related donors, including adoptive parents, and partners of parents of the recipients.
- The transplantation of an organ from a non-related donor within the context of **non-directed living kidney donation**. The donor has no established close personal relationship with the recipient. This includes:
 - o The anonymous volunteers also named truly altruist donors, or “good Samaritan” donors.
 - o Kidney donors involved in a “paired kidney exchange” or a “pooled kidney exchange” donation program for ABO-Type or tissue-type incompatible donor-recipient pairs.
- The **directed donation from an unrelated donor** to a given recipient.

In the **European Parliament Resolution of 22 April 2008 on organ donation and transplantation**, Members of the Parliament

“- Urges the Member States to adopt or to maintain strict legal provisions in connection with transplantation from unrelated living donors, in order to make the system transparent and exclude the possibility of illicit organ selling or coercion of donors; thus, donations by unrelated living donors only being permitted to be made under the conditions defined in national law and following authorization by a suitable independent body.

- Asks Member states to ensure that the anonymity of living donors not genetically or emotionally linked to recipients, where national legislation permits such donations”

The Council of Europe has adopted on 26 March 2008 the **Resolution CM/Res(2008)6 on transplantation of kidneys from living donors who are not genetically related to the recipient**, containing important provisions for living-donor kidney transplantation.

The Committee of Ministers recommends to governments of States Parties to the Convention to take note of the general principles and measures listed in the attached appendix when they draw up the regulations and procedures relating to the donation of a kidney in a view of transplantation by a living donor non-genetically linked to the receiver.

1. States Parties to the Convention may permit the transplantation of kidneys from non-genetically related living donors on condition that:

- the living donor and the recipient have a relationship as required and defined by law; the donor has been given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. The donor has also been informed of the rights and the safeguards prescribed by law for his or her protection, in particular of the right to have access to independent advice about

such risks by a health professional having appropriate experience and who is not involved in the organ removal or subsequent transplantation procedures;

- the living donor has given free, informed and specific consent, either in written form or before an official body; the donor may freely withdraw consent at any time;

- no pressure is exerted on the living donor into donation

- the organ does not, as such, give rise to financial gain or comparable advantage;

- the living donor has been properly screened to identify any physical or psychological contraindications;

- the removal may not be carried out if there is a serious risk to the life or health of the donor;

- long-term medical follow-up is provided to living donors. This includes the monitoring of short-and long-term effects of organ removal on the health of the living donor notably by the establishment of officially recognised registries.

2. States Parties to the Convention may require that persons waiting for such transplants be placed on a national waiting list during the period of approval of the potential donor for donation.

3. Any States Parties to the Convention allowing for non-genetically related living kidney donation should establish a register for such transplants which includes a donor register and donor follow-up procedures in line with those existing for transplantations of kidneys removed from genetically related living donors

4. States Parties to the Convention may permit or prohibit by law non-directed living kidney donations – i.e. “good Samaritan” donors, truly altruist donors or donors involved in a “paired exchange” donation for the purpose of transplantation from a person with no established close personal relationship with the recipient.

5. States Parties to the Convention should establish an independent mechanism for approving non-genetically related living kidney donor transplants in compliance with Article 10 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin. It is also recommended that States Parties to the Convention establish such a mechanism for all cases of non-directed donation. Particular attention should be given to cases where the donor is not a resident of the member state concerned. Within the requirements of data protection legislation, registered activities should be reported on a regular basis to the national health authority.

A majority (8) of the EULID project participating Countries have established legislations or regulations addressing the donor-recipient relationship. Three countries, Cyprus, Norway and Portugal answered to the survey that there was neither regulatory nor legal limitations in the donor-recipient relationship, but in fact unrelated living donor (non-directed and directed) transplantation is not actually performed in these countries. In Romania only, there is no regulatory or legal limitation in the donor-recipient relationship. It is specified that, in case of donation of a minor, a magistrate register its consent.

II.1. Genetically-related donors

Genetically related donors are accepted in all countries, but with limitations in three: Sweden, Italy and France. In France, the law precisely defines the degree of parenthood between donor and recipient. Donation is limited to fathers or mothers, brothers and sisters, children, grand-parents, and cousins of the 1st degree. In Sweden, the practice guidelines limit genetically-related donors to fathers or mothers, brothers and sisters, children and grand-parents. Finally, in Italy, donors are limited to “first grade relatives”, i.e. fathers or mothers, brothers and sisters, and children. However, other donors (including distantly genetically-related and non-genetically related donors) can be taken in to account if no first grade relative is available. In Poland, the next of kin is usually considered for donation.

II.2. Non-genetically, related donors

Partners can be considered without limitation for donation in all Countries, including spouses, legally-registered partners and also non registered partners. For the last category of non-registered partner, four Countries require a minimum duration of relationship of 2 years: France, Cyprus, Romania and Sweden. Legally-related partners, i.e. adoptive parents, and partners of the father or the mother are also considered for donation in all partners Countries.

Friends may be considered as organ donors in a large majority of partner Countries. Only in France and Slovenia, the friends are not accepted as organ donors by the legislation and regulations.

II.3. Non-directed donation of organs from unrelated donors

- Anonymous non-directed donation

Truly altruist donors (“good Samaritans”) are accepted for anonymous donation in a minority of 4 partner Countries: Portugal, Romania, Sweden and the UK. In the UK, the anonymous volunteers are included in a national program and submitted to a specific evaluation performed by the Human Tissue Authority.

- Paired or pooled donation

Paired or pooled (if multiple donor-recipient pairs are involved) living donation may be considered for blood-type or tissue-type incompatible donor-recipient pairs. In Spain, in Italy and in the UK, a national program of cross-over living donation was built under the control of their respective transplant authorities. In Norway Portugal, Romania and Sweden, cross-over donations are not legally forbidden, but not regulated by specific rules. In the other four countries (Cyprus, France, Poland and Slovenia), such non-directed donations are not permitted, those Countries prohibiting any form of transplantation with non-related donors.

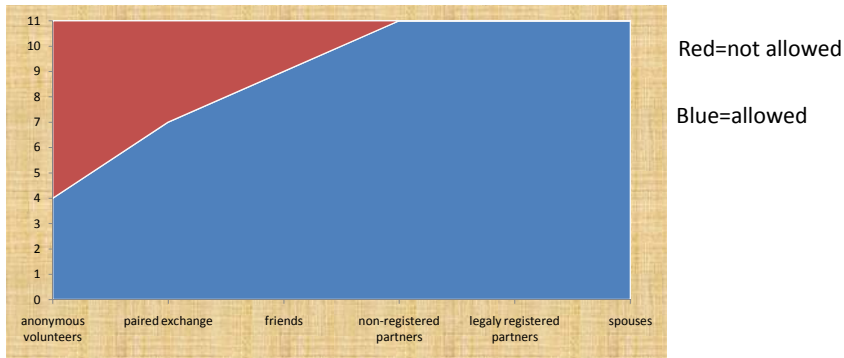
II.4. Unrelated directed donation

In order to prevent commercialism and organ trafficking, directed organ donation from unrelated donors are forbidden in all countries, according to the international guidelines and principles. In Romania however, in the absence of regulation or legislation on donor-recipient relationship, such donations remain theoretically feasible.

The Chart below illustrates the regulations in partner Countries regarding donor-recipient relationship.

GENETICALLY-RELATED DONORS ARE ALLOWED IN ALL COUNTRIES

For the other categories legislation and rules vary widely



In the majority of countries: absence of specific rules

III. INFORMATION, EVALUATION, CONSENT AND FOLLOW-UP OF THE DONORS

III.1. Information for the donor

As stated by the Additional Protocol to the Convention on Human Rights and Biomedicine in the Article 12, Chapter III *“the donor and, where appropriate, the person or body providing authorization, shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks”*.

In most of partner Countries, legislation of regulations require that information for the organ donors should be given by persons or bodies independent from the transplant team. In 7 countries (Cyprus, Italy, Poland, Portugal, Slovenia, Spain and the UK), the information process involves an independent physician (in UK it is the “independent assessor”). In France, the donor committee should be the law deliver information during the interview of the donor before the members of the commission.

In 3 other countries (Norway, Romania and Sweden), there is no regulation on this concern, and information for donors is usually delivered by individuals from the transplant team.

III.2. Evaluation of risks for the donor

The evaluation of risks for the donor is a crucial phase in the process of donation, which is used in the estimation of the risk-benefit ratio of the organ procurement for a given donor within the context of a transplantation which is intended in a given recipient. It results in a statement on the suitability or non-suitability of the possible donor. The evaluation of risks includes the evaluation of the medical risks related to the organ removal and to surgical and anesthetic procedures, as well the psychological and social risks.

As stated by the Additional Protocol to the Convention on Human Rights and Biomedicine in the Article 10, Chapter III *“Before organ removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risk to the health of the donor.”*

The evaluation of the risk for the donor is regulated in most partner Countries. Independent donor committees are involved in Italy, France, Poland, Portugal, Spain and the UK. In Spain and Slovenia, the evaluation process involves an independent medical team. The evaluation of the donor is not regulated in Norway, Romania and Sweden.

Psychological assessment is required by regulations only in Romania, Slovenia and the UK.

III.3. Consent of the donor

As stated by the Additional Protocol to the Convention on Human Rights and Biomedicine in the Article 13, Chapter III *“An organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body. The person may freely withdraw consent at any time”*

Ten partner Countries have in the legislation or in regulations provisions addressing the question of living donor consent. However, procedures for registering the donor consent differ notably according the country. The consent is collected in written form by a regional Court Magistrate in France, Italy, and Spain and in Romania for minors. The donor commission is responsible in Romania and in the UK. An independent physician is involved in Poland and in Portugal (physician under the control of the hospital director), and in Slovenia it is the transplant Authority. In Cyprus and Norway, legislation requires also a written consent.

In Sweden there is no regulatory provision for the registration of the donor consent.

III.4. Follow-up of the donor

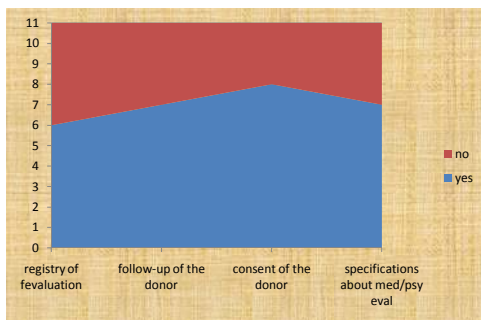
In Portugal, Romania, Sweden and Norway, there is no legal or regulatory provision concerning the medical follow-up of the donor. In the other 7 partner countries, legal or regulatory provisions address to the medical donor follow-up, but not specifically to the psychological follow-up.

On May 2008, a living donor follow-up National Registry is established in Italy, Poland, France, Sweden, Norway (at hospital level) and United Kingdom, but not in Spain, Slovenia, Cyprus, Portugal and Romania.

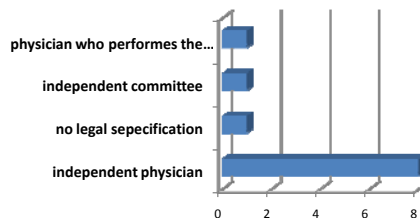
If a donor requires a transplantation following organ donation because of terminal organ failure, partner Countries have not incorporated prioritization in their allocation systems, except in Cyprus where priority is given to the previous donor to receive a national cadaver donor kidney and in Norway where in case of liver failure the liver donor is put in emergency position for receiving a cadaver donor liver procured in Scandiatransplant OSO area. In fact, all donors with liver failure following donation are incorporated in most countries in a “super-urgent” category for liver allocation for patients with acute liver failure.

The chart below shows the disparities between countries according regulations and legislations on processes ensuring living donor protection before and after donation:

Laws or regulations on medical/psychological evaluation, consent and follow-up of the donor and national registry of evaluation are not uniform



The information is generally given by an independent physician



IV. FINANCIAL, ECONOMICAL AND SOCIAL ASPECTS OF DONATION

As stated by the **Additional Protocol to the Convention on Human Rights and Biomedicine** in the Article 21, Chapter VI “*The human body and its parts shall not, as such, give rise to financial gain or comparable advantage. The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:*

- *compensation of living donors for loss of earnings and any other justifiable expenses caused by removal or by related medical examinations;*
- *payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;*

- *compensation in case of undue damage resulting from the removal of organs or tissues from living persons.”*

In the **European Parliament Resolution of 22 April 2008 on organ donation and transplantation**, Members of the Parliament

“- Endorses measures which aim at protecting living donors, from a medical as well as a psychological and social point of view, and ensuring that organ donation is made altruistically and voluntarily, thus ruling out payments between donors and recipients, any payment being confined solely to compensation strictly limited to making good expense and inconvenience associated to donation.

- *Urges the Member States to ensure that living donors are not discriminated against, in particular by insurance systems;*
- *Urges the Member States to ensure the reimbursement of the social security costs of living donors”*

IV.1. Coverage of costs, expenses and compensations of financial losses related to donation

Clinical tests and consultations before and after donation, peri-operative care and hospital stay after donation are fully covered by healthcare systems or insurances in all partner Countries, wherein organ donation can be considered as free of charges for the donors. Travel expenses before and after donation are only covered in France, Norway, Slovenia, Sweden, Portugal and the UK. Financial losses related to the professional activities discontinuation are only covered in France, Norway, Portugal, Sweden, Slovenia, and the UK.

The costs and expenses related to living donation are directly funded by the healthcare system in most of partner Countries: France, Italy, Portugal, Romania, Spain and the UK. In Norway, Poland and Sweden, they are supported by the health insurance of the recipient, and in Cyprus and Slovenia by the insurance of the donor. In Sweden and the UK, payments should be completed by the donor who is then reimbursed, while in the other 9 partner Countries, they are directly completed by the healthcare system or the insurance.

IV.2. Measures to avoid insurance discrimination for the donors (e.g. life and mortgage insurances)

In 3 countries only: Cyprus, Norway and Poland, if a donor contracts a life insurance or insurance for a mortgage, extra-premium related to previous donation required by the insurance company is not allowed. In Slovenia extra-charges are covered by a public fund. No provision is made in other Countries regarding this concern.

IV.3. Compensations for damages related to donation

In case of undue damages related to donation, including morbidity and mortality, no specific provision is made for financial compensation for the donor or his beneficiaries in Cyprus,

France, Poland, Romania, Spain and the UK. Such provisions are present only in Italy, Portugal and Sweden (by public funding), and in Norway and Slovenia (by insurance).

IV.4. Long term care of the donor

There is no specific provision for the long term care of donors, who are generally protected in partner Countries by their respective universal healthcare systems.

Economical and social aspects

➤ The model of comprehensive reimbursement or replacement of costs of living donation is generalized. However, the payment of expenses for arranging and effecting the pre-, peri- and post-operative phases of the donation process (e.g. Long-distance telephone calls, travel, accommodation and subsistence expenses), lost income in relation to donation and lost home productivity is not an unanimous practice.

➤ The provision of disability and life insurance related to donation, and the prioritization on the transplant waiting list in the event of donors requiring transplantation are not generally considered in the law of different countries

