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European Living Donation and Public Health (EULID Project)

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1. Introduction

Donation from alive people has been growing strongly in the recent years, thanks to the advance in the field of organ transplantation and its success as a treatment to procure quality-adjusted life years for many patients with end-stage diseases. The choice of transplantation from a living donor (LD) offers some advantages compared to that for a deceased donor. However, it also carries disadvantages related to donor risks in terms of health and safety, and there are several controversial ethical aspects to be taken into account.

There is no specific pronouncement of the European Union in relation to standards to quality and safety for the living donor process, and there is a great heterogeneity among European Countries legislation, ethical concern, and protection systems and donor's data registries on the topic. The EULID project aims to establish European common standard framework regarding living donor issues to guarantee their health and safety thorough common practices and regulation.

2. What is EULID project?

2.1 General description of the project

The European Living Donation (EULID) project's (<http://www.eulivingdonor.eu/>) was cofounded by the Public Health Executive Agency (PHEA), acting under the powers delegated by the European Commission.

Twelve partners from eleven European Countries have worked cooperatively from April 2007-September 2009, the promoter has been the Hospital Clínic de Barcelona, Barcelona, Spain and partners have been: ANT Fundatia Pentru Transplant, Bucharest, Romania; Centro Hospitalar do Porto, Porto, Portugal; Hôpital Necker, Paris, France; Institute for LifeLong Learning, Barcelona, Spain; ISS-Centro Nazionali Trapianti, Rome, Italy; Paraskevaïdion Surgical and Transplant Center, Nicosia, Cyprus; Poltransplant, Warsaw,

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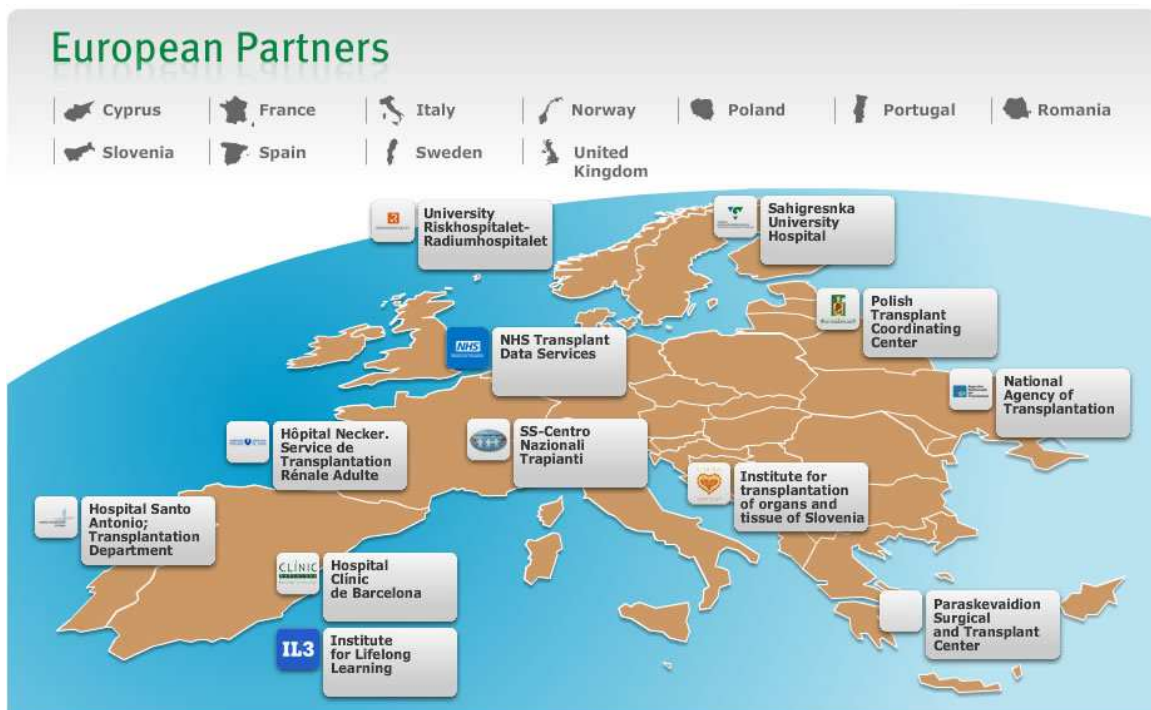


Fig. 1. EULID partners

The main objective was to analyze the current situation among European Union Countries and to contribute establishing common standards regarding legal, ethical, protection and registration practices for organ Living Donors in order to guarantee them the best health and safety scenarios.

2.2 Specific objectives of the project

- To analyze and compare the different European countries legal and ethical frameworks on living donors health and safety in order to establish European legal and ethical recommendations in relation to organ living donors health and safety/on the issue.
- To analyze and compare legislated and non-legislated protection practices on organ living donors health and safety employed in European countries in order to establish European recommendations in relation to living donors health and safety protection practices/on the issue.
- To establish and validate an e-registry database model on organ living donors data that allows having a common European database registry and common national registries on the issue.
- To establish recommendation on a European framework on legal and ethical aspects, protection practices and database registries related to organ living donors in order to guarantee them the best health and safety scenarios in the European Union.
- To disseminate the European action framework/common standards on organ living donors health, safety and protection among professionals and public opinion/general public.

3. Ethical concerns regarding donation of organs from living donors in eleven European countries

3.1 General aspects of living donation ethics

In most issues in medicine in Western countries the two main universal traditions of bioethics are *deontology* and *utilitarianism*. These traditions strongly influence the culture of healthcare professionals and the resolution of codes of practice, regulations and legislations.

Both traditions, while often conflicting, bring different perspectives to ethical controversies, such as those arising in the field of living donation. It is widely accepted that the Beauchamp and Childress' principals' seeks a compromise between general moral theories, and it is accepted as forming the bedrock of medical ethics. They advocate four *prima facie* principles: 1. *Beneficence* (doing well); 2. *Non-maleficence* (avoiding harm); 3. Respect for *autonomy*; 4. *Justice* (fairness). Depending on the context and on whether a deontological or utilitarian approach is favored, a trade-off between principles must be negotiated or achieved. Issues relating to beneficence and non-maleficence lie in the domain of the doctor-patient relationship, and refer more to the deontological tradition. Issues with respect to autonomy and justice apply more to groups of patients rather to individuals and interact more widely with the law, social policy and culture. In the field of living organ donation, all four principles should be given consideration in the different ethical concerns and questions arising.

3.2 Ethical concerns relating to the principles of non-maleficence and beneficence

3.2.1 The principle of subsidiarity

In EU countries having efficient or growing cadaveric donation programs, it is essential that living donation must be an add-on to cadaveric donation, and that promotion of living donation by governments ensure that cadaveric donation is not hampered and is developed to its maximal potential.

Given the only thing that can prevent the promotion of living donation is the risk that implies for the donor, it is essential to keep priority to cadaveric donation. Thus it appears to the EULID participants that the principle of subsidiarity should be maintained, particularly in the case of non-renal living donation.

3.2.2 Benefits for the donor

For the EULID project participants, it should be reemphasized that the benefit for the donor, particularly during the evaluation process of the risk/benefit for the donor, cannot be other than moral, including for unrelated donors (anonymous volunteers and donors involved in cross-over donation programs).

3.2.3 The living donor with higher risk

For the EULID participants, there is a consensus to avoid donation in candidates with higher risk than "standard", including the short-term (peri-operative mortality and morbidity), and the long term (organ failure) risks related to the organ removal. Whatever the donor-recipient relationship, the same medical criteria according to current recommendations

should be applied for the evaluation of the risk in the donor and the definition of contraindications for donation.

3.2.4 Living donation within the context of emergency

For the EULID participants, there is a consensus to recommend that in the situation of liver transplantation in emergency, cadaveric donation should be considered rather than living donation.

3.3 Ethical concerns relating to the principle of autonomy

3.3.1 Restriction of the donor's autonomy

In Europe, it is widely accepted that protection of the potential living donors by legislation and regulations implies restrictions of the donor's autonomy, which is, in the present case, overruled by the principle of non-maleficence. For the EULID participants, there is a consensus for limiting the autonomy of potential living donors by establishing or maintaining legislations or regulations restricting living donation, in order to ensure the protection of the donors, and to prevent organ trafficking and commercialism.

3.3.2 Process of the informed consent and of the assessment of the donor's autonomy

The ethical practice of medicine requires appropriate informed consent for medical procedures. In the case of living donation, informed consent is particularly important since the donor does not receive any medical benefit from the procedure itself, and undertake the possibility of medical risks.

For the EULID participants, there is a consensus for assessing the autonomy of potential organ donors in European Countries by common procedural safeguards including:

- An extensive specific information process of the potential donor who should be capable of understanding the information presented in the consent process;
- The involvement of healthcare professional(s) having appropriate experience and not involved in the organ removal or subsequent transplantation procedure;
- The formal collection of the consent, either in written form or before an official body;
- A reflection period after medical acceptance and decision to donate.

3.3.3 Living donation in non competent minor donors

The United States Live Organ Donor Consensus Group had argued that minors younger than 18 years could ethically serve as live solid organ donors in exceptional circumstances. The Amsterdam forum on the care of the living kidney donor stated the general agreement that minors less than 18 years of age should not be used as living kidney donors. In Europe, the Additional Protocol to the convention on human rights and biomedicine stipulates in Article 14, Paragraph 1 "No organ or tissue removal may be carried out on a person who does not have the capacity to consent"

There is a consensus for EULID participants to exclude non-competent minors less than 18 years of age from consideration for potential organ donation in any circumstances.

3.4 Ethical concerns relating to the principle of justice

Justice is a very important principle in the ethics of transplantation where Demand far exceeds Supply. It applies primarily to the allocation of organs from cadaveric donors, requiring in that context a rank-ordering system with some ethical justification for the method chosen. However, the moral demand for justice has several implications for living donation and transplantation.

3.4.1 Gender inequities in living donor transplantation

The international data presented to the Amsterdam forum on the care of the living kidney donor revealed that approximately 65% of live kidney donors have been women and approximately 65% of recipients have been men. It was agreed that these data on gender imbalance display an excessive disparity, perhaps reflecting a psychological submission of women or discrimination of women in many Countries, including Western Countries. Several strategies have been proposed in order to eliminate gender disparity in transplantation: publish center-specific data, increase education, establish gender-specific support groups, eliminate institutional and provider gender-bias, and promote gender-specific research.

There is a consensus for EULID participants for considering that gender inequities in living donor transplantation should be addressed by promoting targeted strategies at the level of centers and of transplantation agencies.

3.4.2 Impact of donor programs on cadaveric donation

There is a balance in the relationship between cadaveric transplantation and living donor transplantation. There is a consensus for EULID participants for considering that the promotion of living donation must be conducted as a contribution to increase the availability of organs for recipients, and must not undermine the efforts for promoting and developing cadaveric donation.

3.5 Organ trafficking, transplant tourism and commercialism of organs

Numerous reports have highlighted trafficking in human beings who are used as sources of organs from poor people in developing countries, within the context of the global shortage of organs. In 2004, the WHO called on member states “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” (WHA 57.18).

There is a consensus for EULID participants for considering that the general prohibition on organ commercialism by international and national laws should be strictly maintained. Purchasing or offering to purchase organs for transplantation or their sales by living persons should be banned. Laws should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated organs. Incentives in the form of “rewards” with monetary values that can be transferred to third parties, tax reduction or healthcare payment reductions are not different from monetary payments. This does not, however, preclude the reimbursement of reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering organs for transplantation.

3.6 Ethical issues on donor-recipient relationship

3.6.1 Directed donors (genetically and non-genetically related)

From the very beginning there seems to exist a great consensus about genetically-related donors. However this form of transplant is not free from possible coercion. Indeed familiar ties may impose a greater pressure to donate than between friends who may be freer to take an autonomous decision.

There is a consensus for EULID participants for considering that the directed donation of organs from living donors to family members or persons with a pre-existing emotional relationship should be permitted. However, a clear policy that defines the pre-existing emotional relationships that are acceptable must be developed, and the final rule, which technically permits any directed donation of living donor organs to a named person, should be amended to be consistent with this policy.

3.6.2 Directed unrelated donors

This form of donation is more based on emotions than in an equitable allocation system. Also to promote one's cause takes money, so wealthier individuals will enjoy greater success in contacting prospective donors. It is also possible that some intended donors aspire to donate according to race, ethnic, religious or other pattern of preference. Some argue that it's necessary to respect the autonomy of these potential donors and that the utility and the benefit of these procedures would consist in increasing the availability of organs and the quality of life and survival of receptors.

There is a consensus for EULID participants for considering that solicitation of living donors and the directed donation that results may involve unethical and illegal practices that place recipients and donors at risk and should be rejected by the transplantation community. The solicitation of organs from living donors potentially circumvents the principles of justice and utility on which organ-allocation policies are based. Solicitation is not accepted by European Union and by all the transplant societies.

3.6.3 Unrelated non directed donors (NDD)

Non-directed altruistic donors can donate to an unknown patient in the cadaveric list or enter in a paired kidney exchange programme (domino paired exchange for example).

Also of concern is the issue of anonymity. By principle, to avoid the possibility of future coercion over the recipient, it is important to maintain the identification of the donor and the recipient anonymous. After the transplant if both wish to meet or correspond it's better to promote a thorough discussion about the risks and benefits of such a meeting or communication.

There is a consensus for EULID participants for considering that to avoid the possibility of future coercion over the recipient, it is important to maintain anonymity. It is also important the participation of an independent donor advocate promoting the knowledge of the risks and the assessment of the conformity of the evaluation. The registry under the control of health authorities detailing the medical and psychological follow-up is also essential.

3.6.4 Paired exchange programs (and other similar programs)

Resulting from the scarcity of cadaveric organs for transplant some forms of living donor programmes have been implemented. Regrettably not all living related donors are compatible with their intended receptors. As a consequence there are some exchange programs under development that deserve some ethical reflections.

In general, in a paired exchange program the donor who wants to benefit his incompatible (ABO or cross match positive) but related partner (emotionally or genetically) when he is giving to the receptor of other pair is helping also the receptor of the other pair, while he achieves its principal aim that is to help his partner. This is no doubt a fair and equitable distribution of benefits. Also the utility of this action is unquestionable because it allows for two patients to be transplanted and removed from the general waiting list, consequently increasing the likelihood of other patients to be transplanted and therefore improving their access to a deceased donor pool.

But a paired exchange programme puts other generic problems, like those with group O patients. Group O candidates have longer waiting times for transplantation. Also in a living paired exchange programme they are in difficulty because they can be transplanted in a conventional way only if his or her A or B blood type donor can donate to an A or B receptor who is cross-matched positive with his or her O related intended donor. In an unconventional paired donation the blood type O donor 2 will be asked to be more altruistic because he has the possibility to donate to his related donor and he is being requested to make his gift to an unrelated one.

There is a consensus for EULID participants for considering that paired exchange can be accepted when the anonymity is guaranteed and there is an independent body dependent from health authority for the regulation and organization of the process.

In the case that one patient could not receive the kidney beyond the point of no return; there is a consensus for EULID participants that the patient should have priority for a future transplant with a kidney from the cadaveric pool.

4. Legislation concerns regarding donation of organs from living donors in eleven European countries

4.1 Activities undertaken

It was analyzed through a survey among partners the living donor law in partner's countries. If there is specific legislation about living donor, which aspects it regulates, accreditation system for programs for extraction of organs from living donors. This survey gave knowledge about the current situation regarding this issue. All partners answered the survey and all results were analyzed. A report was developed after the analysis, making possible to detect the key points in legislation practice.

4.2 Report on the legislation regarding donation and transplantation

The 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 11 EULID project partner European Countries.

The general legislative and regulatory layout in the field of living donation and transplantation, including the sanctions and penalties applied in case of major violation (i.e. procurement in persons without obtaining consent or in person enable 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 no 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.

4.3 Existing legislation and regulation on financial, economical and social concerns regarding the living organ donor

4.3.1 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 code 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.

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

4.3.3 The European Union

The Commission is planning 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 system in the UE Member States and increase organ availability and fight organ trafficking.

The communication entails 2 mechanism 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.

4.3.4 Specific national regulations

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 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.

4.4 Procedures of authorization for living donation and transplantation activities

In 10 partners countries, the activities of LD procurement and transplantation are legally submitted to an authorization given by health authority to the transplantation centres, 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 (7 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.

4.5 Procedures 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.

4.6 Registration of the donor prior to living donation surgery

Prior registration of living donors at national or regional level to the national transplant authority is required by legislation or regulation in 6 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.

4.7 Non-resident donor policies

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

4.8 Living donor committees/commissions (Localization, dependence, members and role)

All the partners countries except Cyprus have committee/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, Portugal and Slovenia the commission is included in a generic committee (e.g. ethical committee). The commission is generally dependent from the transplantation authority or from the Ministry of Health, but in Italy it is independent and in Spain it is depending from the hospital/university.

The attributions of the committees are markedly different between participating countries. In the majority of countries 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, as well the evaluation of donor suitability. Only a minority of committees plays a role in the information for the donors, directly or by verifying the content and the understanding of information given by the transplant physician.

According to their different attributions, the composition of the committees is also very heterogeneous between the participating countries.

A large majority of commissions includes in their members psychologists or psychiatrists as well. Often, also ethicists are included. In 7 countries the commissions includes physicians, who are transplant physicians in 4 countries. The presence of transplant team representative physicians is allowed only in Norway and UK. In addition, commission may include jurists (3 countries), administrative staff (in 3 countries), social workers (Slovenia, Norway and Spain) and nurses (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 commission 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 centre 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 fig.2 summarize the main Legal and Regulatory dispositions on donation procedures in the partners countries.

Legal and regulatory dispositions on donation procedure

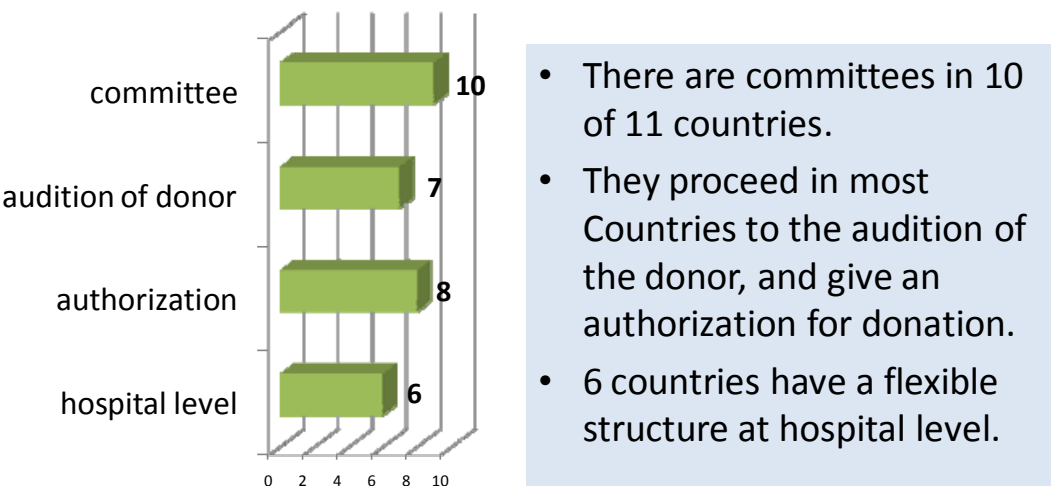


Fig. 2. Legal and Regulatory dispositions on donation procedures in EULID partners countries on donation procedure

4.9 Sanctions and penalties in case of violation of ethical and legal dispositions regarding living donation and transplantation

The convention of Human Rights and Biomedicine, and the additional protocol to the convention of 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 of 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 Actions 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 partners countries, except 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. 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 partners countries. In Cyprus, Italy and Poland however, the procurement in minors/or mentally disabled is not referred, in contradiction to the convention on Human rights and Biomedicine signed by all participating Countries, except the UK.

4.10 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, mother or father, child, grandparent, 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 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 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. These include:
 - The anonymous volunteers also named truly altruist donors, or “good Samaritan” donors.
 - Kidney donors involved in a “paired kidney exchange” or a “pooled kidney exchange” donation program for ABO-Type or tissue-type incompatibility donor-recipient pairs.

A majority of the countries participating in EULID project have established legislations or regulation addressing the donor-recipient relationship. Three countries, Cyprus, Norway and Portugal do not have any regulatory or legal limitation 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 minor, a magistrate register is consent.

4.11 Information, evaluation, consent and follow-up of the donors

4.11.1 Information for the donor

As started 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 partners countries, legislation of regulations require that information for the organ donors should be given by the persons or bodies independent from the transplant team. In 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 by the law deliver information during the interview of the donor before the members of the commission.

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

4.11.2 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 indented 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 anaesthetic procedures, as well the psychological and social risks.

As started 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.

4.11.3 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”.

The 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 to 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.

4.11.4 Follow-up of a donor

In Portugal, Romania, Sweden and Norway there is no 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 when 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 Scandia transplant 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 patient with acute liver failure.

5. Protection concerns regarding donation of organs from living donors in eleven European Countries

5.1 Evaluation of the potential risks for the living donors

5.1.1 General considerations of donor risks

In every living donation setting, the basic principle is that an organ or part of an organ is removed from a healthy individual in order to be transplanted into a needing recipient. The donor and the recipient are usually connected in some way, either genetically (related donation) or emotionally (unrelated donation). Before the surgical procedure, a donor evaluation process is needed to ensure that the potential donor is physically and mentally fit for the procedure, that no contraindications to surgery exists and to rule out any coercion, unethical or financial bindings between donor and recipient. All potential donors with proper motivation, and that have received thorough information are aware that inherent risk are involved in living donor transplantation. After the donation the donor will need a recovery period before his or her preoperative function is restored, and there is a need for follow up both in the short term postoperative course as well as in the long term, to ensure that possible negative events linked to the donation is detected and treated properly. In order to ensure an evidence based practice in living organ donation, data on donor and recipient outcomes should be registered in a systematically manner to allow scientific evaluation of quality and risk of the procedures.

Our current knowledge of the outcome and risks of living donation are based on the practice that has been performed during the last 4 decades in different centres around the world. Of particular importance is the selection criterion that has been utilized. It has been a more or less universal rule, that the donor is healthy, with no signs of disease. Thus, the assessment of risks in this report is based on this assumption. This implies, that the donor evaluation must be focused at identifying individuals that have the lowest possible risk for undesirable outcomes, further underlining the importance of selection in the evaluation process as the fundament of risk management in living donor.

The risks involved in living donation can be divided into the following broad categories, independent of the particular organ donated (table 1):

Risk category	Related factors in donation process
Physical	Invasive tests, donor surgery, post operative complications, organ function short and long term
Psychological	Donor-recipient relationship, recipient outcome, donor postoperative recovery and function, quality of donor evaluation and follow up
Social	Work capacity, family situation, type of work, donor social activities
Economical	Cost associated with donation and follow up, insurance status, sick-leave regulations,

Table 1. Risks involved in living donation

For didactic purposes, it is meaningful to present the risk factors in such a manner, but in clinical practice it is important to recognize that a complication or negative event in

conjunction with the donation might influence any number of the above mentioned risk dimensions.

- Physical risks: The risk of physical complications is related to donor age, general health status and previous history as well as the organ donated. In order to be able to describe complications to the donor surgery, and hence risk in a consistent manner.
- Psychological risk: Several studies indicate that coercion between donor and recipient might be a major risk factor for the mental well being of the donor, and any other motivation that altruistic reasons may have a similar risk of psychological side effects. During the evaluation process, findings that contraindicate donation can be uncovered. Moreover, the motivation of the donor might be altered by the evaluation process itself.
- Social risk: The social risk with regards to role in the family, ability to live unrestricted and have the same work situation is low in most cases. Persons with physically demanding jobs might be particularly at risk in the event of complications to donor surgery. If it can be anticipated that there is an increased risk that the donor cannot lead the same social life after the donor operation as he did previously, the particular subject should be rejected as a donor.
- Economic risk: Several of the non physical factors related to donor risk, are dependent on organizational and legal aspects in the country where the living donation is performed. Social insurance regulations such as the right to paid sick leave and reimbursement of expenses related to travel and limitation in the rights to have life insurance etc., will have an obvious impact on the economical risks associated with living donation. It is also apparent that economic risk factors will influence both the social as well as the psychological risk of a donation.

5.2 Donor protection

The main protection systems for the living donor, regardless of organ are:

1. Careful donor evaluation and selection
2. Use of independent donor advocate
3. Limiting of living donor transplantation to high volume centres
4. Database systems for registration of all donation related morbidity and mortality
5. Perioperative, short term and long term donor follow-up regimens in centres performing this kind of transplantations

None of the above mentioned systems are to EULID team knowledge legislated in Europe or other parts of the world.

Legislative mechanisms that are important in donor protection are:

1. Right to free health care
2. Right to reimbursement of donation related costs
3. Right to sick leave until full recovery after donation, irrespective of length
4. Patient damage insurance systems, providing patients that experience major complications or serious disability with financial coverage.

The legislation regarding the above mentioned factors varies greatly among the European states, as well as how the health system is organized.

5.3 Social insurance and protecting systems for the living donor

Every country has its own systems concerning general social security. Usually the social insurance systems cover everyone that lives and works in that country. It provides financial protection for families, children, for persons with a disability and in connection with work injury, illness and old age. Being a member within European Union, the social insurance benefits in other EU member states, also are available at a certain extent. The living donors should be covered within the systems and our recommendations are given separately.

Social insurance aims to provide security at every stage of life. Throughout the 20th century reforms were gradually introduced and there is still room for improvements and equal rules within EU.

Regarding authorization of sick pay this is made by a physician or the physician of the Social Insurance Office. This seems to be a general rule for all countries.

The employer usually pays for sick leave during the first 2 weeks and then the official authority pays for the remaining period. The amount of payment varies from 60-100% of income, generally 80%.

How long it is possible to be on sick pay varies from 3-18 months in the different countries. Usually some sort of rehabilitation is required and starts usually 6-12 months after start of sick leave and the social insurance usually takes part in this. The rehabilitation is a co-work between different areas. Health care is responsible for medical treatment, the employer for work-related measures and the municipality for social measures.

Pension age varies between 60 and 70 years in different countries and five countries have different ages for males and females according to our survey.

Firing due to sick leave should not be possible but a 3/10 countries have this possibility.

If social-medical insurance is public such a system is easier to regulate. All the partners countries except one have a public system.

5.4 Informative leaflet

5.4.1 General considerations of the informative leaflet

The leaflet developed in the EULID project was translated in 12 languages. It has two different parts with information; one focused on the future kidney Living Donors and the other on the future liver Living Donors.

5.4.2 Contents of the living donor informative leaflet

- Information about the reasons for transplantation and the options to become a donor.
- Donor investigations and selection procedure.
- Surgical approach, normal intercourse and adverse events.
- Psychosocial support and rules for the donors in the evaluating process and after donation period.
- Long-term follow-up.

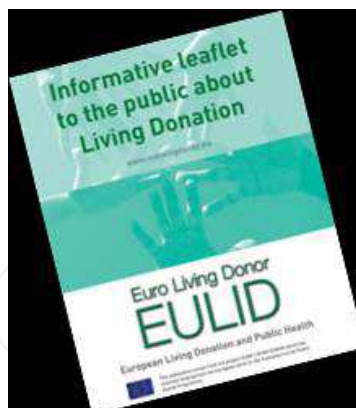


Fig. 3. EULID informative leaflet

6. Living donor registration practices

6.1 Living donor registry

6.1.1 Development of living donor registry

The donation of an organ by a living person to save or transform the life of another is a wonderful act and it is deeply embedded within European law that this should be an altruistic act and consequently it is illegal to trade in human organs or to advertise the buying or selling of human organs. Living donation is complex at the social level with many factors coming to bear upon the decision to donate and the experience of the donor both pre and post donation. The scarcity of organs for use in transplantation and the complexity around the decision to donate and the concerns it may create for the donor and recipient requires that living donation be supported through the creation of an evidence base. The evidence base is required to show that living donation is safe both in the short and long term and that each donation takes place in the form of an altruistic gift and without financial inducement. It is intended that the EULID database and web portal will support the objective to create such an evidence base and so we have started by looking at the donor registration process within the countries participating in the EULID project. The survey has been at a high level to begin to create a picture of the general approach within the EULID project group. The partners of the project created a survey aiming to collect data about the following issues:

- The existence of legal requirements to collect data on living donation
- The existence of a responsible body that holds the data about living donation
- The status of the responsible body
- The type of data reported
- The reporting process

The survey form was sent to a named contact in each EULID Project participating country in order that they could research and report on their national situation. The results were as below:

- Eight countries report that they have a national authority with responsibility for authorising living donation in their country. Two countries, Norway and Sweden report that no such body currently exists in their country and one country did not answer.

- Ten countries report that data about all living donation is collected and held centrally in their country and one country did not answer.
- Five countries report that the data that is collected is at a summary level recording just activity while five countries report that data is reported at the case level. One country did not answer.
- Is there a legal requirement to supply the data?
- In seven countries there is a legal requirement for data on living donation to be reported and in the four remaining countries reporting takes place on a voluntary basis.
- Seven countries report that a transplant coordinator or other member of the transplant team, for example surgeon or physician is responsible for data reporting. In one country responsibility rests with a statistician and in three countries there exists the concept of an Authorised or Responsible person identified to make the reporting.
- Six respondents feel that full reporting is achieved in their country and four respondents feel that reporting in their countries is not fully complete. One country felt unable to express an opinion.
- Seven countries report a system of auditing is in place to monitor reporting compliance and four countries report that no such system is in place in their country.
- In seven countries the data is held by a State body, for example a ministry or other state body such as the NHS in the UK. In four countries the data is held by a body outside of the state such as a university or registry
- All countries record which organ had been donated.
- Eight countries record the nationality of the donor and three do not.
- Nine countries record the country in which the donor is resident and two do not.
- Nine countries record the relationship between the donor and the recipient and one does not.
- Ten countries record the nationality of the recipient and one does not.
- Ten countries record the country in which the recipient is resident and one does not.
- Eight countries record clinical data about the donor, for example complications and survival and three do not.

6.1.2 Data to be collected in the living donor registry database

6.1.2.1 Concept and features of the database

The database is central to the collection of data about living donation and is supplied in a generic format so that it can be used in every country. It is designed to serve the health care professionals who hold the data about living donation activity in their country and who are able to enter this in to the database through a clear and easy to use frontend which can be accessed through the web once the user is set up with an account and access authorized. Additionally the data in the database will be available with “open-access” to the general public who can access data about living donation activity in their country and other countries who contribute data to the database. Through this approach we hope to encourage full participation in the supply of data and to provide the general public with a valuable information resource. We feel that for living donation this possibility is currently unique in concept as we are not aware of any similar facility available with direct access for the general public and healthcare professionals.

Ease of use was an essential prerequisite to encouraging participation and the regular entry of data in to the database. Ease of use is also essential to ensure time efficiency for busy

health care professionals and to support data accuracy. This requirement has been achieved through a clear and logical screen layout, the use of “pick-lists” and real time validation to support the accuracy of data entry. To establish the database it was important to gain a clear understanding of its purpose in order to ensure that the data collected is closely relevant to the purpose of the database and to avoid the burden of collecting data which may not be used. The data is required primarily to support the monitoring of donation activity along with ensuring the safety of the process and high level outcome but it is not intended that the database support any detailed clinical analysis.

The database is founded on a 3 level model. All participants are required to contribute at the “Obligatory” data level, with additional data items categorized as “recommended” and “excellence” being optional.



Fig. 4. Registry model data

Donor confidentiality is maintained within the database concept by ensuring that each donor record is anonym on entry to the database and issued with a unique number.

The website (www.eulivingdonor.eu) has the capability to be used in different languages and is currently presented in both English and Spanish. The language selection is driven by the browser’s configuration. The default language will be English.

Information is displayed on the screen without the need to scroll and information is grouped logically on the screen to aid use with the main element highlighted with a black frame. All pages are protected by session control access.

6.1.2.2 Data items to be collected

Basic data for both living kidney and liver donors (Donor Registration)

- First initial of donor given name
- First initial of donor family name
- Gender
- Year of birth
- Donor country of residence
- Nationality or recipient
- Recipient country of residence
- Relationship of donor to the recipient
- Type of donation

- Organ donated
- Date of donation
- Centre for donation
- Centre for follow-up
- Post operative outcome

This pop-up menu will guide the registering centre to choose alive or death. In case of death, the date of death has to be filled out. This data are necessary to have an idea of the general evolution and outcomes of living donation performed in the EU. Secondly it can bench mark every center to the average result in the EU for every type of donation.

6.2 Summary and recommendations about the strategy to monitor living donors

Based on the preliminary retrospective data input, the EULID database registry has already proven to be a valuable tool for evaluation and comparing trends and quantitative and qualitative data on living donation for both kidney and liver. The high frequency of missing data in both kidney and liver donor subjects, stresses the need of the implementation of an international European database registry in order to evaluate and stratify political, social and clinical regulations and policies. Out of demographic data trends, the registry was able to highlight valuable information on donor and recipient residency, relationship and allocation.

In the interest of monitoring both donor and recipient flow within EU member states as well as the type of allocation, these data registries are extremely important. These factors stress the fact that when trends on European levels should be reported and monitored, a central registry system should be implemented in every EU member state, in order to provide quantitative and qualitative peers to every clinical living donor program within every EU member state, but on top to be able to provide necessary information on a permanent basis to EU health care boards and politicians.

Recommendations about the strategy to monitor Living Donors

- Registration of all living donor cases is mandatory for the purpose of traceability, safety and transparency of activity and outcome of living donor procedures performed within all EU member states.
- Collection of living donor data has to be done through an established central database system, accessible by appropriately authorized persons.
- Data on identification, countries of residency, nationality, type of donation, health care institutions and outcome are obligatory to register, with protection of the donor's proper privacy. An official point of contact has to be made to the embassy of donor's country of residence.
- A regulatory audit is mandatory and data should be both monitored on a national as well as institutional level.

6.3 Living donor satisfaction survey

6.3.1 General aspects

Living donation is a strategy to face the shortage of organs for transplantation, but it requires the protection and follow-up of the donor. The evaluation of donor's satisfaction and the impact of the donation, are key issues to guarantee the quality of the procedure.

The goal of this study is to assess the degree of living donors’ satisfaction with donation and the impact of living donation on donor quality of life.

A living donor follow-up questionnaire including 54 questions has been created according to the Delphi’s method, assaying the following donation related aspects: decision making, information received, stress, impact.

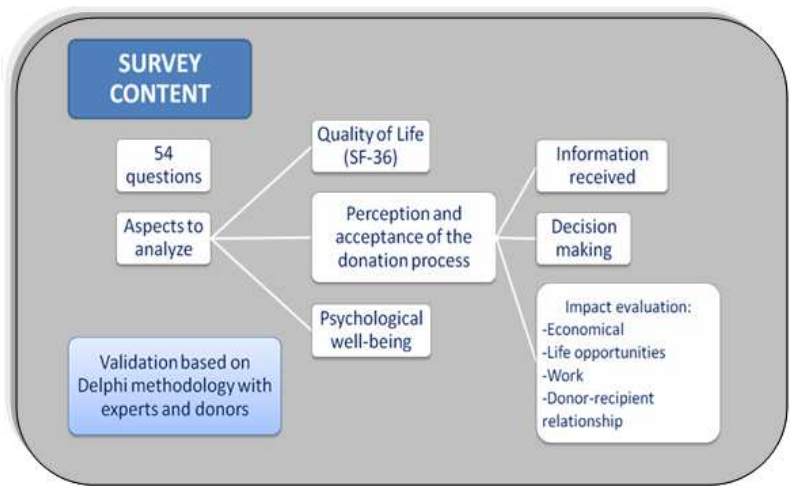


Fig. 5. Living donor satisfaction survey content

6.3.2 Methodology

We have set up a questionnaire on the basis of the ones already available at the Hospital Clínic of Barcelona and reviewed it in terms of content and language. The survey has been designed to explore the following aspects: 1. Perception and acceptance of the donation process, information received, decision making and potential impact of donation on the donor life-style, the ability to obtain future insurability, employment, financial barriers or difficulties donors may face in the donor-recipient relationships. With the support of the Department of Sociology of the University of Barcelona.

The questionnaire, applying a Likert scale from 1 to 4 (Strongly agree, agree, disagree and strongly disagree), has been designed as an agile and easy to use tool for assessment, ordering the questions according to the natural course of the donation process. The original questionnaire has been developed in Spanish, translated to English and from English to each partner country’s language.

Delphi technique has been used to develop the survey which has been assessed by 13 experts, all actively working in living donation as nephrologists, urologists, general surgeons and transplant coordinators. Pilot test was performed on 10 living donors and the following aspects related to decision making and survey behavior were observed: type of reactions, degree of comprehension, spontaneity in answering multiple-choice questions, signs of exhaustion, quandaries and comments. Survey acceptability was high (all participants consented to participate) and questions were clearly understood.

The EULID project targeted living donors at 6 to 18 months after donation as it was considered that donors’ satisfaction < 6 months after donation refers mainly to the surgical procedure while assessment > 18 months after donation does not clearly reveal the decision making and surgical procedure related aspects.

7. Conclusion

The EULID project seeks to contribute to a European consensus that could lead to best practices and to elaborate recommendations that will help to establish a protection framework for living organ donors' health and safety through laws and regulations in the labour, social, medical, and psychological fields. In the same way, the consensus and elaboration of common registries and the recommendations of their application are important improvements to be implemented in the living organ donor field.

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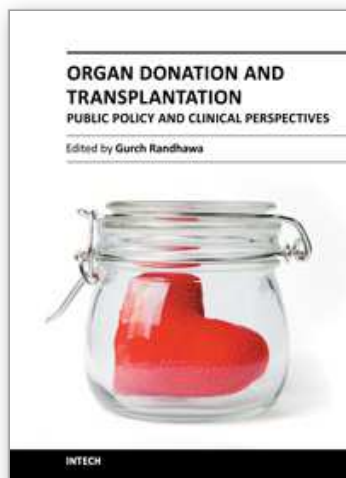
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