

3.1 Publishable summary

INTRODUCTION

The project on living organ donation in Europe (EULOD project) ran from April 1, 2010 until September 30th 2012 and was a coordination action that aimed to 1) establish an inventory of living donation practices in Europe, 2) explore and promote living donation as a way to increase organ availability and 3) develop tools that improve the quality and safety of living organ donations in Europe.

This action aimed to achieve broad European coverage with a specific focus on new EU Member States. 11 partners from 10 different countries were involved. It drew upon the support, knowledge and network of the European platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) and the European Society for Organ Transplantation (ESOT).

To fulfil these objectives, this project contained 2 scientific research packages. The first package focused on living unrelated donation practices in Europe. The second package focused on legal restrictions and safeguards for living donations in Europe. The remaining three work packages ensure the coordination of this work, dissemination of the project results and the organisation of meetings.

Our research activities resulted in 14 deliverables, namely scientific articles, reports and best practice proposals. 7 of these deliverables contain the results and recommendations of our studies. These final results are expected to lead to a better understanding of the issues surrounding living unrelated donation in Europe, and are expected to contribute to the improvement of the quality and safety for human organs, promotion of good medical practices, and the identification of relevant research areas and future needs. Through the research conducted in this project, a better insight was gained in the way European societies deal with the option of living unrelated donation. With this project we respond to EU policy needs, namely the need to communicate and exchange best practices on organ living donation programmes among EU Member States, and the need to enhance organisational models of organ donation and transplantation in the EU member states, in order to relieve the current organ shortage. Currently, with the editing and publication of our EULOD book, we will continue with the same enthusiasm to fulfil our objectives and to maximally disseminate the main findings to all relevant stakeholders beyond the projects end-date.

The project's website can be visited at www.eulod.org or www.eulod.eu.

Scientific Coordinator: Prof. Dr. Willem Weimar,

Project Coordinator: Frederike Ambagtsheer

Organisation: Erasmus MC University Hospital Rotterdam, Rotterdam,
The Netherlands

E-mail: j.ambagtsheer@erasmusmc.nl / Tel: + 31 (0) 10 7033002

CONSORTIUM

The following persons made the results of this project possible:

- **European Society for Organ Transplantation (The Netherlands)**
Prof. Dr. Rutger Ploeg
Dr. Carla Baan
Annalisa Ponchia
Chiara Parisotto
Kate Brooman
- **University of Gothenburg, Sahlgrenska University Hospital (Sweden)**
Dr. Annette Lennerling
Charlotte Lovén
- **The University of Münster, Centre for Advanced Study in Bioethics and BioLaw (Germany)**
Prof. Thomas Gutmann
Dr. Bijan Fateh Moghadam
Leonie Lopp
Ruth Langer
- **Katholieke Universiteit Leuven, Center for Health Services and Nursing Research (Belgium)**
Prof. Fabienne Dobbels
Nathalie Duerinckx
- **Bulgarian Center for Bioethics (Bulgaria)**
Dr. Assya Pascalev
Dr. Adelina Ilieva
Dr. Yordanka Krastev
- **Central European University, Center for Ethics and Law in Biomedicine (Hungary)**
Prof. Judit Sándor
Prof. Violeta Beširevic
Dr. Enikő Demény
Teddy Florea
- **Renal Foundation (Moldova)**
Dr. Natalia Codreanu
Dr. Gaibu Sergiu
Cristina Fleshtor
- **Tartu University Hospital (Estonia)**
Prof. Hele Everaus
Riina Liivand
- **The Academic Society for the Research of Religions and Ideologies (Romania)**
Dr. Mihaela Frunza
- **Polish Coordinating Transplant Center (Poltransplant)**
Dr. Jaroslaw Czerwinski
Dr. Dorota Lewandowska
- **Erasmus MC - University Medical Center Rotterdam (The Netherlands)**
Prof. Dr. Willem Weimar
Frederike Ambagtsheer
Marian van Noord

Discussions about expanding living organ donation in Europe do not occur without debate.

In particular, consensus about the following arguments was not reached:

1. Subsidiarity of living donation versus deceased donation

Pascalev et al. (authors of D5-B) from BCB argue that living organ donation (LOD) should be secondary to other therapies with comparable outcomes for the following reasons:

Firstly, LOD is the only medical treatment, which necessarily subjects a healthy individual (the donor) to pain, harm and risks for the benefit to another (the recipient) and without physiological benefit to the donor¹. This peculiarity of LOD constitutes “the fundamental ethical problem” of LOD². LOD entails physical harm to the living donor by means of surgery and organ removal, risks of infection, postoperative complications, failure of the remaining organ, or even death, and physical and financial burdens such as pain and loss of income.³ The harm, risks and burdens of LOD for the donor could be ethically justified only if the donor autonomously chooses to donate and gives valid informed consent⁴. Yet, donor autonomy and consent, while necessary are not sufficient and do not justify LOD in all circumstances⁵. The autonomous wishes of the donor must be balanced against the risks to the donor’s health and well-being. Additionally, some authors argue that identifiable donor benefit need also be present to justify LOD⁶. The benefit for the donor is defined broadly as psychosocial and/or vicarious benefit⁷. Since such donor benefit is ostensibly present in LOD among genetically and/or emotionally related individuals, LOD among related individuals is less morally problematic than LOD by unrelated (“altruistic”) donors⁸. The three requirements for justified LOD (donor autonomy, informed consent and donor benefit) do not provide automatic uncurbed justification of LOD⁹.

¹ Truog RD. The ethics of organ donation by living donors. *N Engl J Med*. 2005;353(5):444–446; Andorno NB. Voluntariness in Living-Related Organ Donation. *Transplantation*. 2011 Sep 27;92(6):617-619; Caplan A. Do No Harm: The Case Against Organ Sales from Living Persons. In Tan PH, Marcos A, Shapiro R (Eds). *Living Donor Organ Transplantation*. Informa Healthcare, New York. 2007: 435-440.

² Elliott C. Doing harm: Living organ donors, clinical research and The Tenth Men. *J Med Ethics*. 21: 91-96, 1995. See also Spital, A, Taylor J. Living Organ Donation: Always Ethically Complex. *Clin J Am Soc Nephrol*. 2007;2:203-204.

³ The harm and risks of LOD for the donor range from physical pain and discomfort associated with the surgery to possible short and long-term complications and even death. The mortality rate of live kidney donors is relatively low, around 0.03% but it is much higher for live liver retrievals between 0.2%-0.5% [Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (available at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>) (Accessed Sept. 22, 2012); 21; ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures—Surgical), 2004, “Live donor liver transplantation—adult outcomes: a systematic review”]. Other donor burdens include pain, suffering, loss of incomes and the cost of hospitalization and medical care pre- and post-donation.

⁴ Spital A. Donor benefit is the key to justified living organ donation. *Camb Q Health care Ethics* 2004;13:105-109.

⁵ Caplan, 2007; Wilkinson, Martin and Wilkinson, Stephen, “The Donation of Human Organs”, *The Stanford Encyclopedia of Philosophy* (Winter 2011 Edition), Edward N. Zalta (ed.), URL = <http://plato.stanford.edu/archives/win2011/entries/organ-donation>. Accessed Sept. 22, 2012.

⁶ Spital, 2004.

⁷ Wilkinson & Wilkinson, 2011.

⁸ Ross LF, Glannon W, Josephson MA, Thistlethwaite, Jr, JR. Should all living donors be treated equally? *Transplantation*. 74: 418-21. 2002; den Hartogh, G. Farewell to Non-commitment: Decision systems for organ donation from an ethical viewpoint. The Hague: Centre for Ethics and Health. 2008.

⁹ Elliott C. Doing harm: Living organ donors, clinical research and The Tenth Men. *J Med Ethics*. 21: 91-96, 1995; see also Lopp L. Analysing the normative arguments that dominate the policy arena about necessity

They are notoriously difficult to ascertain and remain the subject of intense debates among ethicists¹⁰.

A second, and related, reason supporting the subsidiarity of LOD is that transplantation from living donors contravenes the ethos of medicine and violates the fundamental prohibition against the intentional infliction of harm. The ethical principles of nonmaleficence (“Do No Harm” or *primum non nocere*) is a core principle of medical ethics¹¹. It prohibits physicians from harming the patient intentionally. Removing an organ or part thereof from a health donor is an intentional act, which subjects the donor to pain, harm and risks without physical benefit to that donor thereby violating the prohibition against harm¹². The efforts to justify this violation by appealing to the expected benefit for the recipient and/or society are flawed. As Spital and Tylor note, the attempt to balance the risk to the donor against the benefit of the recipient creates a conflict of interests for physicians asking them to “change the primary focus of their loyalty in a major and, we believe, unacceptable way”¹³ from the interest of the donor to the interest of the recipient. This undermines the fiduciary relationship between the patient and her physician, which is at the core of medical practice¹⁴.

Thirdly, LOD should be secondary to other treatments with comparable outcomes because promoting LOD as the preferred therapy could have the negative effect of distracting medical professionals, researchers and policy makers from seeking alternatives and delaying the development of novel sources of transplantable organs such as stem cell therapy, organ cloning and animal hybrids¹⁵. Also, if LOD is made the treatment of choice for organ failure and a large part of professional efforts and public resources are dedicated to expanding LOD, this could result in one-sided approaches to organ failure, which focus on treatment rather than prevention of such diseases. Therefore, we maintain that while it is important to advance LOD as a means of increasing the supply of organs, it is equally important to focus on the prevention of organ failure altogether, and to seek alternative treatments, which are less invasive and less morally controversial than LOD, which should be secondary to other therapies, when a comparable alternative is available (the subsidiarity principle).

In contrast, Lopp et al. from WWUM (D6,7,8) argue that LOD should not be subsidiary to deceased donation, because:

First, it jumbles the macro- and the micro-level.¹⁶ On the macro-level there is good reason to believe that increasing organ procurement from deceased donors is vital. The availability of a post mortem organ is important because it could be another option for the potential donors. This, however, is no reason to interfere with a living donor’s decision on

and legitimacy of legal restrictions in liver donor transplantation. EULOD Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe, Part I: Unrelated Organ Donation, p. 9.

¹⁰ Andorno 2011, Fellner CH, Marshal GR. Kidney donors: The myth of informed consent. *Am J Psychiatry* 126: 1245-1251. 1970; Caplan 2007; Spital, A, Taylor JS. Living Organ Donation: Always Ethically Complex. *Clin J Am Soc Nephrol*. 2007;2:203-204.

¹¹ Hippocratic Oath, Beauchamp and Childres.

¹² Griffin M, Koenig B, Schears R. Topics in Transplantation. *Transplantation Reviews* 2008;22:151-153; Elliott C. Doing harm: Living organ donors, clinical research and The Tenth Men. *J Med Ethics*. 21: 91-96, 1995; Spital and Taylor 2007, Truog 2005.

¹³ Spital and Taylor 2007, p.203.

¹⁴ Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 6th ed. New York: Oxford University Press, 2009. See also WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. 2010 May. Available from: http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf.

¹⁵ Ross LF. The Ethical Limits in Expanding Living Donor Transplantation. *Kennedy Institute of Ethics Journal*. 2006;16(2):151-172.

¹⁶ Several further points of criticism have already been presented in the first article.

the micro-level inter alia.¹⁷ The recipient himself should – based on his right of self-determination – have the opportunity to decide what kind of organ will be implanted into his body.¹⁸ The donor has a right of self-determination as well. If he is capable of giving valid consent, and does so after being sufficiently informed, the donor's right of self-determination is infringed upon if he is kept from helping a suffering person, even though the intended LOD does not involve any major risks.¹⁹

Secondly, living kidney donation leads to better short-term and long-term results than post-mortem kidney donation.²⁰ As a consequence, the principle of subsidiarity might lead to cases in which the potential recipient is forced by law to receive the worse treatment.²¹

Thirdly, too few donor organs are available. It is, therefore, highly questionable for a patient, who could receive a donor organ from a living person, to be forced to receive an organ donated by a deceased person. Furthermore, this also entails that the next person on the waiting list will not receive that particular organ donated post-mortem.²²

2. Monetary compensation for live donors

Pascalev et al. (D-5B) and Sandor et al. (D9) argue against monetary compensation for live donors. Pascalev et al. (D5 B) state that the idea of paying living donors is morally repugnant and that the mechanisms of the market are not suited for addressing the ethical, cultural, religious and medical complexities of LOD. Although in recent years a number of ethicists and physicians have argued in favour of paying donors as a means to stimulate organ donation²³ and to offset the burdens to living donors, most ethicists, lawyers and transplant professionals disagree.²⁴ The arguments against paying for organs can be divided into intrinsic (deontological and areatic) and extrinsic (consequentialist and empirical). The intrinsic objections view payments for organs as wrong in-and-of-themselves regardless of any possible benefits of such payments. The main deontological concerns are that paying for organs objectifies the donor and her body, and undermines the dignity of the donor²⁵. The main areatic objections center on the professional integrity of providers. The areatic opponents of paid LOD argue that allowing monetary compensation for organs would change the goals of medical practice from healing and palliation to organ trade. This is expected to erode the trust and moral standing of transplant professionals, whose responsibilities would involve organ retrieval for money.²⁶ The consequentialist objections express concerns that paying for organs will lead to exploitation and victimization of the poor, who are most likely to sell their organs. A market for organs calls into question the possibility for genuine informed consent because monetary gain represents a strong incentive for those in need to sell their body

¹⁷ Cf. Gutmann (2006), p. 81 f.; Gutmann, in Middel et al. (ed.) (2010), p. 32 f.

¹⁸ Edelmann, Vol. 50 Versicherungsrecht 1065, 1068 (1999).

¹⁹ Gutmann/Schroth (2002), p. 80.

²⁰ Esser, in Höfling (ed.) (2003), p. 201; Gutmann, in Schroth et al. (ed.) (2005), Sec. 8 at 22; cf. Land/Gutmann, Vol. 35 Transplantation Proceedings 926, 928 (2003); Lilie/Krüger, Vol. 81 Der Chirurg 787, 787 (2010); Norba (2009), p. 60; Schreiber (2004), p. 102; Teubner (2006), p. 5; Ugowski (1998), p. 22.

²¹ Edelmann, Vol. 50 Versicherungsrecht 1065, 1068 (1999); Gutmann, Vol. 15 Medizinrecht 147, 152 (1997); Gutmann (2011), p. 9.

²² Gutmann (2006), p. 74; Gutmann, in Middel et al. (ed.) (2010), p. 33.

²³ Matas AJ. The case for living kidney sales: rationale, objections and concerns. *Am J Transplant*. 2004;4:2007-2017.

²⁴ Caplan 2007, For a review of the objections to paid donation see also, Radcliff-Richards J. Nepharious goings on: Kidney sales and moral arguments. *Journal of Medicine and Philosophy* 21 (4):375–41.

²⁵ Cohen C. Public policy and the sale of human organs. *Kennedy Institute of Ethics Journal* 12 (1):47-64. 2002.

²⁶ Caplan, 2007.

parts. Paid donation is likely to increase social disparities by shifting the supply to those who could afford to pay for an organ from a living donor. Consequently, health disparities would also be exacerbated because those who cannot afford to buy an organ may opt out of participating in the organ donation system altogether. This will result in overall decrease rather than increase of available organs.²⁷ Other considerations against paid LOD are that such a practice would be offensive to numerous religious and cultural groups and would alienate large segments of society.²⁸ Other consequentialist objections include a decline of altruism in society and decline in the quality of donated organs²⁹. The consequentialist arguments receive support from the available empirical data on markets of organs in countries such as India. This data shows that purchased organs have high failure rates and that the transaction does not improve the socio-economic circumstances of paid donors and often diminishes their health and self-esteem³⁰. Therefore, we conclude that market relations and commodification of organs from living donors are morally unacceptable.

Sándor et al. (CEU) agree with Pascalev et al. (BCB), claiming that necessity and exploitation cannot legitimize organ sale. We think that European human rights norm enacted in the Oviedo Convention and its Protocol that provide a good direction of national legislations. Furthermore, we are in agreement with scholars, such as Donna Dickenson who argues that if we lose decision making autonomy in our bodies, then we *lose a part of our individual identity*. As it follows even the poorest person should enjoy the same right and respect to his bodily integrity as the rich even if he/she does not have *any other* property just his/her body. We think that by granting organ sale (organ for money) we *devalue altruism*. In Iran where organ sale is legitimized (only within the country) altruism was compromised by the possibility of organ sale. As the Nuffield Council recommends, in line with European law (both within the Council of Europe and the European Union), “*giving bodily material because another person needs it underpins a communal and collective approach where generosity and compassion are valued.*” In sum, *altruism* should continue to play a central role in the ethical and legal thinking on organ donation. The best way to guarantee autonomy, identity, autonomy, and dignity if one can decide to offer a kidney to a relative or to a friend but if one have no other choice for survival, only passing his/her kidney to someone for money then the act of “giving” diminishes personal autonomy, dignity, and eventually identity. If someone suffers from the possibility of losing a close relative, organ donation seems to be a sacrifice worth doing. If other benefits are given to the organ donor in the form of health services, then it should be done in a manner that avoids foreclosing altruism. It should be considered unfair for the organ donors if they are unable to receive the necessary health care service when they need it later in their lives and possibly die in the lack of financial support. Nevertheless, their future health care needs should be uncertain at the moment of donation, and should not be taken as a condition for the act of donation. In addition to some health care benefits to the altruistic donors it is also important to mention the need for legal policy that cultivates and promotes altruism. Love and care are probably the best and most powerful incentives for organ donation. Therefore, if additional benefits are given to the organ donor in the form of health services, then it should be done in a manner that avoids foreclosing altruism. International organ sale exploits and further

²⁷ Caplan. 2007.

²⁸ Stempsey, WE, Organ markets and human dignity: On selling your body and soul. *Christian Bioethics*. 6(2): 195-204. 2000.

²⁹ Munson R. Organ Transplantation. In Steinbock B (Ed.) *The Oxford Handbook of Bioethics*. Oxford University Press, NY. 211-239, p. 225.

³⁰ Goyal M, Mehta RL, Schneiderman LJ, Seghal AR. Economic and health consequences of selling a kidney in India. *JAMA* 2002; 288: 1589-1593. See also Scheper-Hughes N. Keeping an Eye on the Global Traffick in Human Organs. *The Lancet* 361 (May 10, 2003), 1645-1648.

discriminates people because the transaction is essentially based on unequal development and unequal distribution of resources and health care. Furthermore, organ sale arrangements often leaves (or sends back) the “donor” in a country where adequate postoperative health care is not available.

Ambagtsheer and Weimar of EMC disagree with an absolute prohibition of organ sales. For this reason they retracted as co-authors from the publication by Sándor et al. In contrast to Pascalev et al., and Sándor et al, they argue amongst others that prohibition generates black markets, drives up prices, provides illegal incomes, displaces crime to other regions and drives trade underground leading to higher crime rates and victimization. They outline their arguments in, *Ambagtsheer, F. and Weimar, W. A Criminological Perspective: Why Prohibition of Organ Trade is not Effective and How the Declaration of Istanbul can Move Forward, American Journal of Transplantation;12(3): 571-575 (2012).*

3. Living donation by minors and mentally incapacitated adults

Pascalev et al. argue against live donation by minors and mentally incapacitated adults, because these groups lack autonomy and do not have capacity to consent due to cognitive limitations. This prevents them from meeting the primary ethical requirement for justified LOD – the free and autonomous consent of the donor. Those who argue in favour of organ retrieval from living incapacitated individuals face a dilemma: they must either claim that informed consent is unnecessary for LOD, thus making the case also for conscription of competent persons³¹, or they must claim that LOD is justified on different grounds, i.e., by the best interest of the minor or incapacitated donor. Both alternatives are implausible: the idea of non-voluntary LOD and universal donor conscription violates the deeply entrenched moral and political values of individual autonomy and self-determination. The attempts to justify LOD by minors and mentally incapacitated adults by appealing to their best interest are also unsuccessful because the concept of best interest cannot be applied to mentally ill individuals who have never been competent.³² Furthermore, it is questionable whether a live organ donation can ever be in the best interest of a minor given the high risks of the procedure and the irreversible nature of the act. As Pascalev argues elsewhere, LOD by minors threatens not only their physical well-being but infringes on their future autonomy because the donation limits the minor’s future opportunities to donate to a spouse or child. Lastly, those who argue in favour of retrieving organs from minors could maintain that the capacity for consent is a matter of degree and that some minors demonstrate enough maturity to provide consent for LOD. We acknowledge that the maturity of minors is relative, fluid, individually-specific and varies by age. Respectively, we adopt the sliding scale approach to assessing the required level of competence for informed consent for LOD. The sliding scale approach reflects the current state of knowledge about competence as a dynamic state linked to individual experience, maturity and well-being.³³ The sliding scale approach requires to raise the threshold of competence for high risk procedures and to lower it for low risk procedures. LOD is a high risk procedure with irreversible long-term consequences for the donor and therefore it requires a high level of maturity and experience characteristic of adulthood. Based on the above arguments, we maintain that LOD from minors and mentally incapacitated individuals is morally unacceptable and should be prohibited to prevent these vulnerable groups from harm.

³¹ Wilkinson and Wilkinson, 2011.

³² Buchanan AE., Brock DW. *Deciding for Others: The Ethics of Surrogate Decision Making*, Cambridge: Cambridge University Press. 1989.

³³ See Beauchamp and Childress, 2009, p. 116; see also Buchanan and Brock, 1998, p. 51-52.

Lopp argues against an absolute prohibition, but claims that cases might exist in which LOD by a minor is ethically justifiable.³⁴ A complete prohibition does not take the differences between more or less mature minors into account.³⁵ Therefore, the most suitable approach to regulate LOD of minors and mentally incapacitated adults is to assess the person's capability individually. Since minors and mentally incapacitated adults can also be protected sufficiently by established, clear legal requirements, under which they may act as living organ donors, a less restrictive approach seems preferable.

RECOMMENDATIONS

1. Living Organ Donation Practices in Europe – Results from an Online Survey (D4)

In work package 2 a web-based survey was sent to 45 European countries, to investigate the prevalence of living organ donation, which types of living organ donation are conducted in each centre and which ethical, legal, financial and practical barriers are encountered to perform or increase the number of living organ donations. Furthermore, the survey aimed to gain understanding in how potential living donor candidates are screened and how follow-up is conducted. The extensive contact list, to which the survey was sent, contains names and addresses of key transplant persons in almost all European transplant centres and has been developed in collaboration with ELPAT and ESOT.

Data was collected from 113 kidney transplant centres from 40 countries and 39 liver transplant centres from 24 countries. In total, 25 out of the 27 EU-member countries were represented by kidney transplant centres and 18 by liver transplant centres. Out of the 18 non-member states contacted, we received replies from 15 countries regarding the kidney donation survey, and from 6 for the liver donation survey. The majority of the responders were transplant surgeons, nephrologists and transplant coordinators. Four of the replying centres did not have a living kidney donor programme and 11 did not have a living liver donor programme.

The results, published in a peer-reviewed international transplant journal, provides evidence that the growth of living donation, a necessary practice to reduce morbidity and mortality for patients on the waiting list, still depends on the policy of a single country. It confirms that there are extensive differences transnationally and regionally. It concludes with the following recommendations:

- Consensus should be reached within Europe which major medical contra-indications to be used, based on empirical evidence and follow-up data of live donors and recipients.
- Centres should demonstrate sufficient volume of surgical procedures and training (especially live donor nephrectomy) to ensure a high level of surgical skills, and state of-the-art care for the living donor.
- Reimbursement should be offered to all living donors. Governments should be made aware of what is legally acceptable and the EU should encourage them to implement these policies.
- Irrespective of centre volume, donor quality and safety could be increased by documenting serious adverse events and morbidity. National or European

³⁴ Cf. Gutmann/Gerok, in Collins et al. (ed.) (1997), p. 319; cf. Gutmann/Schroth (2002), p. 55.

³⁵ Cf. Gutmann/Gerok, in Collins et al. (ed.) (1997), p. 319; cf. Gutmann/Schroth (2002), p. 55.

mandatory registries could be a platform to do so, although the content and consequences of such registries need to be carefully discussed and adopted by the European transplant community, taking historical, economic, cultural and healthcare system-related factors into consideration.³⁶

2. Expanding Living Organ Donation in Europe: Attitudes, Barriers and Opportunities. Results from Focus Groups conducted in four European Countries (D5-A)

Four focus groups have been conducted in countries with low living donation rates: Estonia, Bulgaria, Belgium and Romania. The aim of these focus group interviews was to better understand potential barriers towards living organ donation. Transcripts were prepared and translated to English. The qualitative data was organised using software NVivo Version 9, and the results were analysed by the researchers. Our findings generate important new knowledge about the attitudes, barriers and moral reasoning regarding living organ donation among European transplant professionals and other stakeholders in Europe, which can serve as a basis for future research and policy discussions on this subject. This study revealed the existence of similarities, but also significant differences concerning LOD in these countries. The low rates of LOD were attributed to demographic, financial or medical factors. No religious or legal barriers to LOD were reported. Harm and risks to live donors were major ethical concerns. LOD to anonymous recipients was viewed negatively because of its potential for commercialization. Lack of resources and lack of public awareness were cited as barriers in the new EU member states. Independent Ethics Committees were viewed as important for donor protection. The analysis showed that raising public awareness, and government support and investment in LOD are needed to improve LOD. The focus groups findings offer a basis for future studies of LOD in Europe and may inform policies and strategies for improving LOD in these countries and the EU. Based on these data, we outlined 12 recommendations for increasing LOD in Europe:

1. To increase the rates of LOD in Europe, wide public and political support for LOD needs to be built.
2. Transplant professionals, who are largely supportive of LOD, represent a main resource for building social support because they have the expertise and social visibility to influence other actors. Thus transplant professionals could be the agent of change in the public, professional and policy domain.
3. The conservative attitudes to LOD among some health professionals need to be changed by educating providers about advances in LOD on an on-going basis.
4. National registries of living donation and transplantation should be implemented in all countries to allow for a long term follow-up of donors and recipients, and to generate data about the outcomes of LOD.
5. Because of the importance of the well-being of donors, the safety of LOD should be improved continuously. The positive results should be publicized in the professional and public domain.
6. Broad public support for LOD should be built by ongoing education of the public and by employing all media channels while taking into consideration the sensitive nature of LOD and the privacy and confidentiality of the donors, recipients and their families.

³⁶ Publication: Lennerling, et al. Living Organ Donation Practices in Europe-Results from an Online Survey, *Transplant International* 2012;26(2): 145-153; forthcoming in: Ambagtsheer, F and Weimar W. (eds), EULOD Project. Living Organ Donation in Europe: Results and Recommendations. Lengerich: Pabst 2013.

7. For LOD to become a viable component of the health care system, it needs the support of the government especially in the EU member states, which should be encouraged to make LOD a public health priority and to allocate adequate funding and build modern infrastructure for LOD programs.
8. Due to the particular importance of informed consent in LOD, mechanisms for in-depth screening of living donors and recipients should be developed by independent local or national bodies such as independent ethics committees with participation of members with diverse backgrounds and expertise reflecting the multifaceted nature of LOD, e.g., medical, psycho-social, ethical and religious backgrounds. Ethics Committees, which are independent from transplant professionals could act as facilitators of the free and unbiased assessment of potential donors and should have a central role in the LOD process.
9. Provider burnout should be addressed to relieve the pressure on transplant professionals caused by the risks of LOD and need to balance conflicting responsibilities to donors and recipients.
10. Programs to promote LOD should be sensitive of the conflict inherent in LOD, which inevitably involves physical harm to an otherwise healthy individual.
11. Because of the risks and potential harm to the living donor, whose risks and harm cannot be linked to comparable benefits to the donor, nor can they be morally justified solely on the basis of donor autonomy, proponents of LOD should recognize that LOD may indeed constitute a sensitive and controversial area that divides public opinion and does not lend itself to a definitive solution.
12. In view of the moral challenges inherent in LOD, public policies based on the principle of subsidiarity might be a promising tool for gaining broad public and political support for LOD while also exploring alternative treatments, which could offer superior or comparable benefit-to-burden ratio, all things considered.

The results of this study provide important information about the existing barriers to LOD in EU member states in which LOD is legal but its rates remain low. The study also sheds light on the attitudes of transplant professionals and other stakeholders to LOD and on their concerns and needs. These insights could be useful in the development of future interventions, educational programs and policies to encourage LOD. This information could help to develop strategies for overcoming the obstacles and increasing LOD in EU. It could serve as a basis for future research into the ethical, cultural, legal, financial and other aspects of LOD in Europe. The complexities of LOD, which surfaced throughout the study, are likely to have broader relevance for the future of LOD in Europe confirming the insightful statement of the previously cited FGD participant: *“Transplantation is at the limits of human capacity, at the limits of science.”* (P2, Bulgaria).³⁷

3. Ethical Analysis of the Arguments for and against Living Organ Donation (D5-B)

We used the data from the descriptive work in D5-A for an in-depth analysis of the normative aspects of living organ donation. The aim was to assess these justifications and to analyse ethical arguments in support of living organ donation. The ethical analysis of the arguments for and against LOD established that:

- There are solid moral grounds to justify LOD by appealing to the principles of autonomy, beneficence and justice.

³⁷ Pascalev et al. Transplantation (submitted); forthcoming in: Ambagtsheer, F and Weimar W. (eds), EULOD Project. Living Organ Donation in Europe: Results and Recommendations. Lengerich: Pabst 2013.

- The above principles do not provide unqualified justification for LOD without regard of the moral responsibilities of the physician or the moral status of the donor.
- LOD can be justified in a limited way as a practice open to autonomous individuals who voluntarily consent to the risk and benefits involved in LOD.
- Some donor benefit must be present to offset the harms and risk to the donor
- LOD requires strict safeguards to establish valid consent, benefit to the donor and conflict-free assessment by a fiduciary-physician.
- Vulnerable populations such as minors and mentally incapacitated individuals do not meet these requirements and therefore LOD from minors and mentally handicapped individuals is not morally permissible
- The moral principle of justice requires LOD to include some form of benefit for the donor, which may be broad enough and may include psycho-social, moral and material benefits. However, monetary compensation for organs is morally repugnant for then number of reasons stated in the literature against organ sales.
- Market relations and commodification of organs from living donors are morally unacceptable.
- LOD will inevitably involve some burden to healthy donors and as such has to be secondary to other therapies, when a comparable alternative is available (the subsidiarity principle).³⁸
- Given the moral and medical complexities of LOD, we recommend that developing LOD goes hand-in-hand with exploration of new technologies which would allow transplantation to progress with greater success and fewer moral challenges.³⁹

4. Analysing the Normative Arguments that Dominate the Policy Arena about Necessity and Legitimacy of Legal Restrictions in Living Donor Transplantation (D6)

5. Comparative Analysis of European Transplant Laws Regarding Living Organ Donation (short and long version (D7))

6. A Best Practice Proposal on Legal Safeguards for Living Organ Donation in Europe (D8)

D6 contains a critical analysis of the core normative arguments that dominate the policy discussion about the necessity and legitimacy of substantive restrictions of the donor-recipient relationship in living donor transplantation. With the help of legal experts across Europe, including experts from ELPAT, transplant laws from all European countries were collected. D7 presents these laws and reconsiders all legal requirements for living organ donation. In addition, it emphasises the donor-recipient relationship and procedural safeguards. D6 and D7 provide the basis for a proposal for policies and best practice with regard to legal restrictions. This proposal contains the following recommendations (*summarized version*):

³⁸ The argument given against payment and commodification of organs, and the argument given in favour of subsidiarity of living donation, reflect the individual opinion of the authors of D3 and not that of other participants in this project.

³⁹ Pascalev et al. Ethical Analysis of the Arguments for and against Living Organ Donation, forthcoming in: Ambagtsheer, F. and Weimar, W. (eds), EULOD Project. Living Organ Donation in Europe: Results and Recommendations. Lengerich: Pabst 2013

A **harmonisation** of the national regulations concerning LOD is desirable. We have established a best practice proposal for LOD, or a *Common Frame of Reference for European Laws on Living Organ Donation (CFR-LOD)*. This best practice proposal for LOD has been established from the following sources: conclusions drawn in chapter 4, through a consideration of the common principles laid down in the *CFREU* and an examination of the relevant general national laws.

1. The donor's **informed consent** is absolutely necessary, and in a few countries it is even sufficient to justify LOD. A best practice regulation must consequently explicitly require the donor's **consent**. He must have the competence to consent, and his consent must be given voluntarily. The minimum formal requirements include: an appropriate amount of time for the donor to reconsider his decision and a written consent. A best practice regulation should not contain any additional mandatory formal requirements. Even after the donor has given his consent, he may withdraw it at any time. This must be explicitly mentioned in the best practice regulation and the donor must be informed about this option. The donor's informed consent can under no circumstances justify LODs that cease his life or would be directly life-threatening. No further limit on the legal ability of donors to give consent should be stipulated by law. The recipient has to give consent as well.

A valid informed consent requires the **disclosure** of the donor. A best practice regulation should clearly present what the donor has to be informed about. The whole (medical) procedure and potential risks should be explained to him. The donor should be informed about alternative therapies for the recipient, about the prospect of success and the risks for the recipient. The donor should be mandatorily informed about any additional, foreseeable circumstances that are relevant to him. The donor needs to understand the information provided to him. With respect to the person providing the disclosure, the physician who performs the intended transplantation has to inform the donor, and another physician with no part in the transplantation process should be present as well. The recipient should also be informed, namely, about his health and about the donor's health and risks, because recipients usually only accept limited risks for the donor.

2. The **transplantation must be suitable**. The best practice proposal should contain a **risk-benefit equation** without providing very detailed or paternalistic requirements, leaving the decision to the autonomous donor (and recipient) and transplant team.
3. A best practice regulation would not absolutely prohibit **minors** and **mentally incapacitated adults** from becoming living organ donors, but would contain specific requirements that only allow them to donate a kidney in very exceptional cases.⁴⁰ The minors or mentally incapacitated adults informed consent is necessary. The person concerned must have the capacity to give informed consent. Additionally, the parents or the custodian of persons of full age must give their consent. Donor and recipient must have a close personal relationship. Living kidney donation by a minor or a mentally incapacitated adult must remain the *ultima ratio*, and, furthermore, an independent commission must give its approval.

⁴⁰ This argument reflects the individual opinion of the author of D6 and not that of other participants in this project.

4. A possible **restriction of the donor-recipient relationship** has been rejected after impartially reviewing the key arguments in this debate. Besides our review, we also found that restricting the donor-recipient relationship is not aligned with the *CFREU*. We advise against distinguishing between relationships; instead, the concrete risks involved in each individual case should be evaluated. A best practice regulation should, consequently, not contain a restriction of the donor-recipient relationship, but should require case-by-case decisions. With respect to different models of LOD, such as cross-over LOD and unspecified LOD, there is hardly a reason for *legally* banning them. However, these types of LODs can only be performed if a sufficient national scheme has been established. Whether the countries or national transplantation systems choose to do so is their decision alone, but there are many good reasons for establishing such policies.
5. LOD should not be **subsidiary** to post-mortem donation.⁴¹ Post-mortem donation should, however, never be regarded as secondary to LOD. With respect to the relationship between LOD and alternative therapies, LOD should be the *ultima ratio*, but a patient suffering from kidney failure should not have to depend on the worse option of dialysis, even though LOD is possible. The Swiss regulation that states “[o]rgans, tissues and cells may be removed from a living person if: [...] the recipient cannot be treated with any other therapeutic method with comparable benefit” should be adapted.
6. Several **procedural regulations** are recommendable as safeguards for LOD (“**Safety by procedure**”). Most countries have established some kind of procedure and an independent **commission** as a safeguard for LOD. Four different categories with respect to procedures can be classified among the countries considered. (1) Some countries have not established legal procedures for LOD. These countries often establish procedures at the hospitals/transplant centres themselves, though. This is recommendable for countries with hospitals/transplant centres that are professionally well-developed and take an active part in the ethical and legal discussions related to LOD. (2) Another idea would be to stipulate rules by law for decentralized procedures that take place at the hospitals. This approach might make it possible to combine the advantages of a legal rule with the advantages of innovative and pluralistic procedures established by the hospitals themselves. (3) Another approach is a system of multiple, state-run commissions or commissions defined by public law, where the procedures are only partly regulated by federal law. This could lead to legal uncertainty because the details differ in the federal states. (4) Other countries have created a central state commission by law. This has the advantage that the same working methods and criteria are applied nationwide, guaranteeing legal certainty and equal treatment of comparable cases. This is, in comparison to the third approach, more consistent and is more likely to provide “safety by procedure”. Due to the pre-existing diversity among the countries considered, it is impossible to unify the national approaches just introduced. Additionally, a commission should consist of independent experts from different professions to examine and, as far as possible, ensure the voluntariness of the donor (and the recipient). It should apply consistent criteria in an equal manner. In the countries that do not consider the donor’s consent as sufficient to justify LOD, the commission must also authorize every LOD. Appropriate **post-care** for donor and recipient should be explicitly stipulated in a best practice regulation. The *Directive 2010/45/EU on Standards on Quality and Safety of Human*

⁴¹ This argument reflects the individual opinion of the author of D6 and not that of other participants in this project.

Organs intended for Transplantation requests that “[m]ember states shall endeavour to carry out the follow-up of living donors [...]” The Netherlands is a trailblazer for donor and recipient post-care procedures because its legislation now encourages living organ donors to undergo regular check-ups after the LOD. Also, a **donor registry** that records perioperative complications and impairments is necessary to ensure continual post-care and to increase the amount of relevant information contained in future medical disclosures.

7. Since LOD is very expensive and is no therapeutic treatment for the donor, **social security regulations** should be very extensive, eliminating the donor’s financial responsibilities. The donor should be protected in the best possible way; he should be completely carefree. The Swiss regulation demands the surgeon who removes an organ from a living person to ensure that the person concerned is insured against any potential serious consequences connected to the organ removal. It holds the insurer liable who would have to compensate the recipient’s costs for his illness if no LOD were available. Additional details have been specified by the Federal Council in Art. 11 *Transplantation Ordinance*. Since the Swiss rule is very extensive, it can be used as a model for social security regulations. With respect to the **reimbursement** of living organ donors, a survey done by EULOD WP 2 revealed that the practical situation is very insufficient, numerically 54 % of the included kidney donors, and even about 70 % of the considered liver donors, were not reimbursed. Hence, that all the donor’s possible expenses resulting from the LOD have to be reimbursed must be explicitly regulated. The Swiss regulation can again serve as a model. There, the recipient’s insurance company is explicitly responsible for all costs and for an “appropriate compensation for loss of earning or other expenses incurred by the donor in connection with removal.”⁴²

7. Improving the Effectiveness of the Organ Trade Prohibition in Europe (D9)

This study consisted of an analysis of the current legislation on organ trafficking and tourism and its effectiveness, and on the current status of trafficking and tourism in Europe and neighbouring countries. Various organ trafficking and transplant tourism cases in Europe have been collected. This occurred through stakeholder interviews, media analysis and archival research. Cases were identified in Romania, Moldova, Ukraine, Belorussia, Bulgaria, Serbia-Kosovo and the Netherlands. These cases were subjected to an in-dept analysis. Material collected by the Serbian War Crime Prosecutor’s Office has also been analyzed.

The results of our research across a wide range of European countries have confirmed that, while legal provisions repeatedly emphasize and reinforce the principles of non-commercialization, a law is not an omnipotent tool. In the lack of appropriate control and follow-up mechanisms within the organ transplantation system and without the support of the professional bodies of medical practitioners, the growing economic tension between the poor and the rich may lead to finding legal loopholes and organizational gaps within the enforcement mechanism. However, the research has also identified good practices and promising efforts in regional co-operation that have contributed to the enhancement

⁴² Lopp, L. Living Organ Donation in Europe – Possibilities of Harmonisation. PhD thesis and forthcoming in: Ambagtsheer, F. and Weimar, W. (eds), EULOD Project. Living Organ Donation in Europe: Results and Recommendations. Lengerich: Pabst 2013 (forthcoming). The three reports are also available online at www.eulod.eu.

of the existing organ transplantation systems. The results of our research are a contribution to these positive developments with a special focus on the improvement of legislative and law enforcement mechanisms.

This study presents the following recommendations:

1. Raise awareness about the Crimes of Organ Trafficking Should Be Enhanced with the Involvement of Enforcement Institutions;
2. Provide Non-Punishment for the Victims of Trafficking;
3. Provide Criminal Immunity for Impoverished and Vulnerable Sellers;
4. Develop Law Enforcement Policies to Suppress Trafficking in Human Beings for Organ Removal;
5. Adopt measures for the explicit criminalization of organ trade;⁴³
6. Strengthen the responsibilities of health professionals towards the victims of organ trafficking, trade, or tourism (to organ providers);
7. Strengthen the responsibilities of health care professionals in case of organ tourism (organ receivers);
8. Health care providers should dissuade patients from seeking organs abroad;
9. States and professional associations should develop professional guidelines for professionals who may be in contact with organ tourists;
10. Develop instruments for the prevention of organ trade and organ trafficking;
11. Empower Ethics Committees involved in Living Organ Donation decision making.⁴⁴
12. To increase the earlier identification of victims of organ trafficking, by implementing the pro-active approach of identification process;
13. The assistance measures should be adequate to the real victim's needs and should include the long term medical follow-up.⁴⁵

⁴³ This argument reflects the individual opinion of the authors of D7 and not that of other participants in this project.

⁴⁴ Sándor et al. Organ Trafficking. Organ Trade. Recommendations for a more nuanced legal policy, forthcoming in: Ambagtsheer, F. and Weimar, W. (eds), EULOD Project. Living Organ Donation in Europe: Results and Recommendations. Lengerich: Pabst 2013.

⁴⁵ Enikő Demény, Frederike Ambagtsheer, George Teddy Florea, Judit Sándor, Natalia Codreanu (ed.), Violeta Beširević, Willem Weimar "Improving the effectiveness of the organ trade prohibition in Europe. Recommendations", Chisinau, 2012. This report is also available online at www.eulod.eu.