The EULOD Project
Living Organ Donation in Europe
Results and Recommendations
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The researchers were helped by members of ELPAT during two EU-funded working group meetings in Sofia, Bulgaria (2010) and Berlin, Germany (2011). ELPAT is the European platform on ethical, legal and psychosocial aspects of organ transplantation. It is an official committee of the European Society for Organ Transplantation (ESOT).
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Introduction

EULOD: Living Organ Donation in Europe

Living organ donation is increasingly introduced by transplant centres as a valuable alternative to bridge the gap between demand and supply of organs. Living organ donation poses opportunities, but also involves ethical, legal and psychosocial implications. Moreover, there is large heterogeneity among European countries in terms of living donation rates, ethical concerns, legislation and protection systems for living organ donors.

The project on Living Organ Donation in Europe (EULOD), a Coordination Action funded by the Seventh Framework Programme of the European Commission, was a response to this European heterogeneity and to the urgent policy needs expressed by various EU institutions.

The project started in March 2010 and ended in September 2012. It aimed to establish an inventory of living donation practices in Europe, explore and promote living donation as a way to increase organ availability, and to present recommendations to improve the quality and safety of living organ donations in Europe. Eleven institutions from ten different European countries were involved. The partners collaborated closely with the European platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) and the European Society for Organ Transplantation (ESOT).

This book presents the study results of this project. The results range from describing living organ donation practices across European countries, highlighting opinions and conceptions of individuals towards living donation, exploring ethical arguments for and against living donation, analyzing European transplant laws regarding living organ donation, to scrutinizing the current prohibition of organ trafficking and transplant commercialism in national and international law.

Discussions about expanding living organ donation in Europe do not occur without debate. The aim of this project hence was not to achieve consensus on ethical principles that accompany the expansion of live donation. The arguments presented in the six papers express the individual opinions of the authors and not of that of the consortium.

We are grateful for the commitment of all partners in this project, and would like to thank each of them for generating an output that is unique to this field of transplant medicine.

We trust that you will read our work with great interest. It is our hope that our results and recommendations will contribute to your every day practice, and that they will help you to consider ways in which living organ donation can be expanded safely and ethically in countries worldwide.

Rotterdam, February 2013

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Living Organ Donation in Europe – Clinical Praxis*

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Introduction

Since the early fifties, organ transplantation has been one of the most rapidly evolving areas in medical science, resulting in excellent survival and quality of life. This success is mainly due to the development of immunosuppressive drugs, better medical treatment including prevention of infections and rejection, improved organ preservation and surgical techniques. Transplantation, however, became the victim of its own success, resulting in far more patients being admitted to the transplant waiting lists than can be transplanted annually.

The organ shortage presents one of the major challenges in the field of organ transplantation today. In 2011, 49,477 persons were on waiting lists for kidney transplantation and 6,808 for liver transplantation in the 27 European Union (EU) countries (502 million inhabitants), while during the same year 18,712 kidney transplantations and 7,006 liver transplantations were performed [1]. The lack of organs for transplantation results in long waiting times for the patients in need and a high risk of dying before a suitable organ becomes available [2, 3]. Depending on blood type and other medical aspects, the average waiting time for a deceased donor kidney in Europe today is 3–5 years. Mortality rates among those waiting range from 15-30 % depending on organ, and approximately ten people die every day in the EU waiting for an organ transplant [4]. Despite strategies to enlarge the donor organ pool, such as adopting presumed consent systems and widening deceased donor criteria, the worldwide organ shortage persists.

Given the failure to meet the growing need for organs obtained from deceased donors, the use of living donors has increased, a fact also recognized by the European Commission in 2007 in its Communication on organ donation and transplantation [4]. In that paper, major policy challenges were identified, including organ availability. In 2008, the European Commission consequently adopted a proposal for a directive that defines quality and safety requirements for human organs intended for transplantation. This proposal was subsequently adopted by the European Parliament and on July 7, 2010 by the Council [5]. Paragraph 23 of this directive states that ‘living donations need to be performed in a manner that minimises the physical, psychological and social risk to the individual donor and the recipient’. It further mentions that ‘The potential living donor has to be able to take an independent decision on the basis of all the relevant information and should be informed in advance as to the purpose and nature of the donation, the consequences and risks. In this context, […] the highest possible protection of living donors should be ensured’ [5, p 17]. In the light of recent cases of organ trafficking, the directive also stipulates that such unacceptable practices constitute serious violations of fundamental rights and, in particular, of human dignity and physical integrity.

Living organ donation (LOD) has long been an established practice in many European countries, and recent advances have been made regarding surgical methods, screening and selection of donors [6-11]. In 2011, 20.6 % (0-61 %) of all kidney transplants and 3.5 % (0-50 %) of all liver transplants performed in the European Union were using a live donor [1]. However, large differences across European countries in the rates of living donation can be observed (Figure 1). The Netherlands, Norway and Sweden are among countries with high rates of living kidney donations (LKD), whereas Poland, Finland and Belgium have low rates [1] and a few countries lack a LKD programme (e.g. Luxembourg & Montenegro). The barriers and incentives to conduct living donor, kidney or liver transplantations are not well understood. Differences between countries also exist regarding relations between donor and recipient that are acceptable, screening for potential donors and donor follow-up. Hence, it is currently unclear how European countries put the EU directive into practice to guarantee donor safety.

The aims of this study were to:
1. Survey the various practices of LOD in Europe
2. Identify possible legal, ethical and financial considerations that act as barriers towards LOD
3. Achieve full European geographical coverage
Methods

Design and sample

This is an exploratory survey and a descriptive cross-sectional design was used. Transplant professionals from kidney and liver transplant centres in all EU member states were invited to complete an online survey. Transplant units in non-EU member states were also invited when contact information was available. Only liver and kidney transplant centres were considered, as lung-, bowel- and pancreas transplantations from living donors are mainly in an experimental phase and are rarely being performed. To guarantee maximal response from as many transplant centres as possible no other specific inclusion or exclusion criteria were stated. Ethical approval to conduct the survey study was obtained from the ethical review board of the KU Leuven in Belgium February 24, 2011.

Development of the survey

Two separate, but similar questionnaires were constructed for living liver donation (LLD) and for LKD. A copy of both surveys is published on the EULOD website [12].

With permission of the authors, we used a survey on the selection of LKD in the US as the basis for our questionnaires [13]. The content was revised after extensive literature search, by iterative rounds of review and through pilot testing of the surveys by two transplant professionals. The questions focused on the prevalence and types of living donation performed, possible barriers towards living donation, the medical and psychosocial screening of donor candidates and follow-up.

In the literature, varying terminology for living organ donation can be found. In the survey various types of donor and recipient relations were listed, in all 17 alternatives (table 4 a), e.g. sibling, friend and stranger. However, we saw a need for a new classification to avoid confusion. Therefore we first assessed the existing terminology in the light of current living organ donation practices and thereafter suggested a more straightforward classification [14]. This was done in close collaboration with the Working Group on Living Organ Donation in the association Ethical Legal and Psychosocial Aspects in organ Transplantation (ELPAT a section of European Society on Organ Transplantation). We proposed to concentrate on the degree of specificity with which donors identify intended recipients and to subsequently verify whether the donation to these recipients occurs directly or indirectly. According to this approach, one could distinguish between “specified” and “unspecified” donation and within specified donation, a distinction can be made between “direct” and “indirect” donation (Table 1). This classification was used in the analysis.

The surveys were built in the online data collection software programme, called examinare© (www.examinare.com). The forms that examinare© creates are protected by Secure Socket Layer (SSL) and the information between server and browser is encrypted. The surveys were only created in the English language. This was decided for two main reasons: 1) the costs for producing surveys in several languages were not in the budget and 2) the international scientific language is English.

Procedure

The networks of the EULOD consortium, ELPAT, European Society of Organ Transplantation (ESOT) and some informal transplant networks were used to create a list with names and e-mail addresses of transplant professionals in liver and kidney transplant centres within Europe. This was done in order to get access to at least one centre within each EU member state, although maximal coverage was aimed for i.e. one reply from each existing transplant centre in each country. The same networks were used to reach out to non-member states in which transplant activities take place. From
March 2011 to December 2011, in total 331 letters of invitation to participate in the study were sent to kidney transplant professionals and liver transplant professionals in 45 countries. The letters included information on confidentiality and were sent together with a link to the online survey. A minimum of three reminders were sent to those who did not respond.

Nominal and ordinal results are presented as percentages. All responding centres were grouped into three geographical regions: North-Western, Mediterranean and Eastern. Responses between regions were compared (statistical analysis Chi-Square for nominal and Kruskal-Wallis testing for ordinal variables were used, statistical software SPSS version 19.0, statistical significance was set at p < 0.05).

Results

By January 2012, 113 kidney transplant centres from 40 countries and 39 liver transplant centres from 24 countries had completed the survey. 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 six 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 eleven did not have a living liver donor programme. Table 2 shows the numbers of responding centres from each country that were approached.

Living kidney donation

Living donor programmes for kidneys were practiced in all responding EU member states, and all but two responding non-member states. The majority of kidney centres (60 %) performed less than 25 LKD transplantations a year, 28 % between 26 and 50 while 12 % did more than 50 and of those, two centres did more than a hundred (The Netherlands and Turkey). When dividing Europe into three geographical regions, living kidney donation was performed in all responding centres in the North-West and in the Mediterranean region but not in all centres in the Eastern region (Table 2). Less than 25 LKD transplants per year were performed in 81 % of centres in the Eastern region, 73 % of Mediterranean centres as compared with 45 % in the North-Western region, while the volume of transplantations from deceased donors were about the same in all three regions.

Most centres applied a donor age of 18 years as a minimum, but eight centres (7 %) also accepted minors as donors. An upper age limit was defined in half of the centres and then most often set at 70 or 80 years. A specific question about women in childbearing age as donors was asked. In 21 % of the centres they were excluded as donors and 3 % excluded women with young children.

Defined limitations for medical conditions precluding donation, e.g. body mass index (BMI), hypertension, diabetes or proteinuria, are shown in Table 3 (divided in the three European regions). The Eastern centres used less strict medical criteria for donors compared to the Mediterranean and North-Western regions. Diabetes type 1 was considered an absolute contraindication in 75 % of the centres in the Eastern region versus 97 % in North-Western. For diabetes type 2 the figures were 59 % for Eastern versus 77 % for the North-Western. A potential donor with a BMI over 40 was an absolute contraindication in 87 % of centres in the Mediterranean and 89 % in the North-Western regions compared to 75 % in the Eastern centres. For the 24 h urine protein of > 300 mg the greatest discrepancy was between the Eastern centres and the Mediterranean. This was an absolute contraindication for donation in 56 % of the centres in the Eastern region versus in 73 % of the centres the Mediterranean. Potential donors with well controlled treated hypertension were to a higher grade accepted in the North-Western centres, in 63 % of the centres versus 50 % in the Eastern.
A general method to evaluate kidney function is to measure the glomerular filtration rate (GFR). Normal results range from 90–120 mL/min/1.73 m², but GFR decreases with increasing age and therefore older people will have lower GFR levels. GFR was measured in the screening process of potential donors in all but four centres. A cut off limit was set at 80 mL/min per 1.73 m² body surface area in 42 % of the centres, at 75 mL/min in 18 %, at 70 mL/min in another 18 % and at 65 mL/min in 21 % of the centres.

Regarding specified direct donation (Table 1), i.e. donation from a person directly to an intended recipient, psychological screening performed by psychiatrists or psychologists, was included as a routine in the pre-donation evaluation in two thirds of the centres. In most other centres it was completed when problems were identified or suspected. Psychiatric disease or personality abnormalities were taken seriously and constituted absolute contraindications in the vast majority of centres. The results from the questions in this survey on psychosocial screening will be described and discussed in depth and submitted to a scientific journal for publication.

Specified direct donation was the predominant relation between donor and recipient in all centres. The vast majority of centres accepted parents, siblings, adult children, grandparents, other genetically related family, spouses and partners. Most centres also accepted in-laws and close friends (68 % and 69 % respectively). Specified indirect donation – i.e. when the donated kidney was used in an exchange programme, where the intended recipient received a kidney from another donor – was practised by almost half of the centres (43 %), (Table 4 a).

The type of specified LKD donations accepted varied in different parts of Europe: many Eastern countries did not accept donation to a genetically unrelated but emotionally related recipient other than spouses, while in the North-West friends and acquaintances were often accepted. Furthermore, centres in Mediterranean and Eastern countries less often accepted grown up children as donors than North-Western countries (Table 4 b).

During the last decade unspecified (anonymous) donation has become accepted in some European countries. Unspecified kidney donation was performed in one third (32 %) of the transplant centres responding (Table 4 a). In four centres, the anonymous donor was also allowed to define certain recipient characteristics, e.g. children (i.e. The Netherlands, Denmark and Sweden). Select a certain recipient was allowed only in one responding centre (The Netherlands).

Specified indirect LKD programmes (paired exchange programmes) and unspecified (“anonymous”) programmes had started during the last decade in 41 centres (36 %) in 13 countries (10 EU-member states, 3 non-members). In most centres, ten or less such donations had been performed since the start, but two centres – one in the Netherlands and one in Turkey – reported to have performed more than 50 cases each. The medical screening was the same as for specified direct donors in 18 of the 41 centres. Additional screening for the unspecified (“anonymous”) or specified indirect LKD (paired exchange programmes) was included in more than half of the centres and generally consisted of more extensive psychiatric or psychosocial evaluation.

While preparing the donor, information about the LKD was generally given both verbally and in writing. Audio-visual information techniques, such as DVD’s or web sites, were used in 39 % of the centres. In most centres the information included legal conditions, the evaluation process, the surgical procedure, expected recovery period, possible short and long-term donor complications as well as risks involved for the recipient. Regulations on reimbursement for e.g. income loss were comprised in the information given in 65 % of the centres. Informed consent prior to donor nephrectomy was required in all transplant centres.

Several surgical techniques are used for the living donor nephrectomy. In this survey we defined four groups; 1) open surgery with flank incision and rib resection, 2) open surgery with an anterior approach, 3) laparoscopic technique and 4) robotic technique. More than one surgical technique was used in a number of centres. The laparoscopic technique was used in 66 % and the open flank incision with rib resection was in use in 29 %, (Figure 2). In respect to the different European regions the open flank incision with rib resection was more commonly used in the Eastern centres.
than in the North-Western and Mediterranean centres, 57 % versus 12.5 % and 14.5 %. In contrast, laparoscopic techniques were used in 81 % of the North-Western and 50 % Mediterranean centres versus 37 % in the East (Table 3 and Figure 2).

Reimbursement for income loss during hospital stay and sick-leave period to kidney donors was not given at all in 54 % of the centres. Reimbursement to donors was clearly less given in the Eastern and Mediterranean regions (Table 3).

All but three centres (Croatia, Lithuania and the Russian Federation) offered postoperative follow-up and in 67 % it was reported to be life-long. The check-up included medical tests in all centres and psychosocial evaluation in 17 %. Follow-up was incomplete in 84 % of the Eastern centres, but was performed in all North-Western and Mediterranean centres. Donor data registers were kept by 92 % of kidney centres. Only 20.5 % also reported to European registries. The Eastern centres (81 %) tended to keep registers less often than the North-Western (97 %) and Mediterranean centres (93 %). The items most frequently reported in the registers, apart from identity and relation to the recipient, were pre-operative medical information and post-operative complications.

**Living liver donation**

We received in total 28 responses from living liver donor programmes in 18 member states and in five non-members states (Table 2). Living liver donations were more frequent in the North-Western region than in the Eastern and Mediterranean.

Two-thirds of the 28 reporting liver centres performed five or less living liver transplantations a year and the remaining centres never performed more than 25.

Specified direct donation was predominant in all centres, the vast majority accepting parents, siblings, adult children, grandparents, other genetically related family, spouses and partners. Most centres also accepted in-laws and close friends as liver donors, 50 % and 61 % respectively. Specified indirect donation – in an exchange programme – was an accepted practice in six of the 28 centres and unspecified (anonymous) donation in seven. However, only eight such donations had actually been performed, in seven centres representing four countries. Any anonymous donor was permitted to define certain recipient characteristics in four centres and to select a certain recipient in three centres (Table 4 a).

All centres had a lower donor acceptance age of 18 years, while an upper age limit was set in 57 % of the centres, most often at 60 years. Women in childbearing age were accepted as LLD in 83 % of the centres, while 17 % excluded them. Few medical conditions would preclude LLD and most often they were considered to be only relative contraindications. Liver steatosis in the donor was accepted in a range varying from none in three centres to more than 10 % in seven centres.

Psychological screening, performed by a psychiatrist or psychologist, was included as a routine in the pre-donation evaluation in 82 % of the centres and otherwise when problems were identified. In analogy with kidney donation, psychiatric disease or personality abnormalities were taken seriously and seen as absolute contraindications in almost all centres.

As for the kidney donors, information on the LLD was given both verbally and in writing, and the contents were similar. Regulations about reimbursement for e.g. income loss were included in 70 %. The majority of the liver donors, 68 %, did not get any reimbursement for income loss and other expenses.

Informed consent was obtained prior to surgery in all centres. All but one centre had a medical follow up for the liver donors postoperatively. In nine centres this was intended to be life-long. LLD registers were kept by all 28 centres, but only five of them reported to European registers.
Barriers to living donation programmes

Four (3.5 %) of the responding 113 kidney transplant units and eleven (28 %) of 39 liver transplant units lacked a living donor programme. Thus, the number of replies to the question about possible barriers to living donation was small. The four centres which did not have a LKD programme were all about to start programmes and no barriers were identified. Regarding the eleven transplant centres lacking LLD programme the reasons mentioned were:

a) financial barriers
b) no need due to sufficient supply of livers from deceased donors
c) it had never been discussed in the transplant centre
d) a negative attitude among health care professionals to such programme
e) a lack of surgical expertise

For specified indirect donation – in an exchange programme – and unspecified (anonymous) donation for both kidney and liver donation the barriers stated from the few responses were:

a) these donations are illegal in the country
b) these donations were thought to be unethical and could not be justified
c) a negative attitude among transplant professionals, other health care professionals and within the society
d) financial reasons and lack of resources

Discussion

As far as we know, practices in living organ donation in European countries have not been studied previously making this an unique study. In total, responses were obtained from 40 European countries (89 %) out of the 45 countries contacted with kidney transplant programmes and from 25 countries with liver transplant programmes. Responding transplant professionals represent centres from both from EU member states and non EU members. For the EU member states close to full coverage was achieved with responses from 25 out of 27 countries. Although most EU member countries are performing LKD, the rate per million people (pmp) shows a great discrepancy (Figure 1). For instance in 2011 Finland had 2.4 LKD transplants pmp and Italy had 3.5 LKD pmp respectively, The Netherlands had 26.3 LKD pmp and Sweden had 19.6 LKD transplants pmp [1]. This shows that there is a large potential for increasing the number of LKD in many EU countries.

Donor selection and safety

The study showed that some aspects related to donor selection and safety, were not always guaranteed. Selection criteria are not uniform and sometimes not sufficiently restricted. The World Health Organisation states in their guiding principles on Human cell, tissue and organ transplantation from 2010 that, “Live donations are acceptable when the donor’s informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion” [15, p. 3]. Further, in the EU directive for quality and safety for human organs intended for transplantation requirements are stated to ensure protection of the live donor [5].

Our results showed that one fourth of the centres in the Eastern European region did not consider diabetes type 1 as an absolute contraindication for kidney donation (Table 3). This is clearly not
in accordance with the above mentioned directives on safety and quality since diabetes mellitus is a common diagnosis leading to end stage renal failure. Another risk factor for the donor is obesity. Potential donors with a BMI above 40 were accepted in 25% of the kidney transplant centres in the Eastern region. Due to most international guidelines this is considered to be a contraindication for kidney donation. Additionally GFR at 65 ml/min was an accepted level for LKD in as many as 21% of all responding centres. It has been recommended for a potential donor to have a GFR of 80 ml/min as the lowest level, though the potential donor’s age has to be taken into consideration as well [16].

Several randomized studies have demonstrated that laparoscopic techniques are safe for live donor nephrectomy and are to be preferred over the open approaches [17-19]. Laparoscopic techniques have several advantages for the donor; less pain, shorter hospital stay and a shorter recuperation time [20]. The results of this survey clearly demonstrate that in many centres especially in the Eastern countries, the laparoscopic donor nephrectomy still needs to be implemented (Figure 2). Training programmes for laparoscopic donor nephrectomy have been developed for this purpose.

Many European centres perform few live organ donations annually. For LLD our results show that 63% of all centres performed five or less donor hepatic lobectomies per year. This activity requires high level of surgical skills and great understanding of the vascular and biliary anatomy of the liver [21].

We also found large disparities regarding LKD between European regions, with a low volume of LKD transplantations in most Eastern and Mediterranean centres. It appears to be a highly prestigious activity in many ways for hospitals to have a transplant programme. To ensure a high enough surgical volume a centralisation of programmes using living organ donors for transplantation could be beneficial. This would also enable the transplant team to develop the highest level of skills in all phases of the donation process and most probably improve donor safety.

Reimbursement

A remarkably high number of the responding centres did not offer the donors reimbursement for income loss or other costs. Kidney donors were not reimbursed in 54% of the centres and the liver donors not in 68%. This finding reflects the reluctance of governments in Europe to implement compensation and reimbursement policies for the living donors. The World Health Organization guiding principles permits reimbursement for “reasonable and verifiable expenses incurred by the donor, including loss of income” [15, p. 5]. The European Convention on Human Rights and Biomedicine also states that the prohibition of financial gain “shall not prevent payments which do not constitute a financial gain or a comparable advantage” [22]. We believe that many countries may not be aware that offering compensation and reimbursement of costs is legally acceptable. The lack of reimbursement and compensation should not be a reason to discourage persons to become live organ donors. All donors should be offered the possibility of compensation and reimbursement of costs made that were a (direct or indirect) consequence of their donation. The Competent Authorities in EU Member States and other European countries should be made aware that the above mentioned compensations are legitimate and in line with international rules and guidelines. Furthermore, they should be encouraged to put in place appropriate reimbursements for living donors.

Follow-up

Most centres in this study indicated that they had follow-up programmes and generally registers on living donor follow-up were kept, though one third of the kidney transplant centres did only keep the register in the centre and did not report on a national level. As for any surgical procedure living
organ donation involves risk for morbidity and mortality [21, 23–25]. We argue that medical and psychosocial follow-up programmes and registers of living organ donors should be mandatory. This is also fortified by the WHO Guiding Principles, the Declaration of Istanbul and the EU Directive on standards of quality and safety of human organs [5, 15, 26]. To increase the knowledge about the long term consequences of living organ donation and to guarantee safety for future donors, lifelong follow up is required. Registries on living organ donors should be implemented and regularly monitored on a national level. These registries should, at a minimum, include information concerning serious adverse events and reactions after donation [5].

Barriers to living donation

The few responses given in this study regarding possible barriers for increasing living donation were e.g. financial barriers, a negative attitude among health care professionals towards such programmes and lack of surgical expertise. Today the financial barrier seems challenging to overcome due to the economic crisis in many European countries. However, living kidney transplantation is by far more cost-effective than dialysis treatment [27]. It has been shown that kidney transplantation leads to a cost benefit in the second and subsequent years [28]. Although renal transplantation is not the main treatment for end stage renal failure, it is the treatment of choice, with lower costs and better outcomes [29]. Liver transplantation is a life-saving therapy, since there is no medical procedure designed to prolong or substitute the liver function, comparable with dialysis for end stage renal failure. The benefits for the liver recipient with transplantation cannot be disregarded.

According to the sixty-third World Health Assembly 2010, “donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations” [15, p. 3]. We argue that it is necessary that nephrologists and hepatologists develop a positive attitude towards living organ donation, as they play a crucial role for transplantation to become reality for even more patients in need of a new organ. To use live organ donors for transplantation is a prerequisite in addition to deceased donation to overcome the organ shortage.

In this study, acceptance of relation between donor and recipient throughout Europe has been explored for the first time. The most common relations accepted were parents, siblings, other genetically related and spouses. Although not shown in our results as barriers, various legal and societal hurdles towards several types of donation, for instance, unspecified donation or specified direct donation to a stranger, exist in many countries. There are opinions recommending the removal of these barriers and focus on “safety by procedures” [30]. This process depends to a great extent by the willingness to modify restrictions within every country. To partake in cooperative activities such as the EULOD project, may possibly open the discussions in these states and encourage them to give up these restrictions. This might result in a change of attitudes.

Methodological limitations

We attempted to reach a complete coverage of the EU member states. Of the 27 member states 25 responded to the LKD survey, but the responses were not equally distributed over the area. Quantitative analyses comparing conditions in different states could therefore not be made.

Another limitation might have been that centres without a living donor programme were less likely to reply. Furthermore, the fact that the survey language was English seems to have been an obstacle in parts of Europe. Despite our efforts in contacting numerous transplant centres (n = 331), there were few responses especially from the Mediterranean region and also from some states in Eastern region.
Recommendations

The European Commission puts organ donation and transplantation high on their policy agenda and strongly supports the use of living donors to increase the organ availability for transplantation. A prerequisite is that a legal framework is in place and that safety can be guaranteed for both the donor and recipient [5].

In line with the EU directives [5] and as a result of this study the following is suggested to improve the quality and safety of living organ donation as well as an increase in the general organ supply in Europe:

- There is a need to utilise the existing potential of living organ donation as one resource to decrease the imbalance between the demand and the supply of available organs for transplantation.
- A harmonisation of practices in Europe built on scientific research and evidence based guidelines is necessary. Medical contraindications to donation should be agreed on, e.g. diabetes type 1 should disqualify for living donation.
- Living donor programmes should be focused to lesser number of units in each country to enable sufficient volumes. This enables a high level of surgical skills as well as development of expertise in all phases of the donation process. Surgeons performing live donor nephrectomies should be adequately trained in laparoscopic techniques, through hands-on courses or fellowships/proctorships, to be able to deliver state-of-the-art care for the live kidney donors. Obviously, surgical training should be obtained to permit live donor liver transplantation at all.
- Reimbursement should be offered to all living organ donors for loss of income during hospital stay and sick leave, preferably also for expenses during work-up and recovery. Non-reimbursement may form a major obstacle to many potential donors. Governments should be made aware of what is legally acceptable and they should be encouraged by the EU to implement these policies.
- Follow-up of living organ donor morbidity (and mortality) should be mandatory. The follow-up results should be documented in National and/or European registries. These registries should publish the results on a regular basis e.g. every other year. The minimum threshold should be the reporting of serious events.

Acknowledgements

We would like to wholeheartedly thank the following persons:

All transplant professionals in Europe taking part in this study,
James Rodrigues, for letting us use the survey performed in the US on medical screening of living kidney donors as an inspiration when constructing our survey,
The ELPAT working group on Living Organ Donation, for identifying the living organ donation classification and helpful comments when constructing the surveys,
All ELPAT members, for assisting in finding key transplant professionals within Europe,
A special thanks to Consultant Nurse Lisa Burnapp in London UK, for assisting in sending surveys in the UK,
Dr Leonie Lopp (EULOD Work Package 3 part 1), for helpful comments and suggestions on the manuscript drafts,
Mrs Marian van Noord, secretary of ELPAT, for support and for assisting in finding key transplant professionals within Europe,
Bibliography


Table 1. Classification for living organ donation defined by the working group Living Organ Donation in the association Ethical Legal and Psychosocial Aspects in Organ Transplantation [14].

<table>
<thead>
<tr>
<th>Specified donation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct donation: when a person donates directly to his or her intended recipient.</td>
</tr>
<tr>
<td>donation to a genetically and emotionally related recipient (e.g. mother to child)</td>
</tr>
<tr>
<td>donation to a genetically unrelated but emotionally related recipient (e.g. spouse)</td>
</tr>
<tr>
<td>donation to a genetically related but emotionally unrelated recipient (e.g. estranged father)</td>
</tr>
<tr>
<td>donation to a genetically and emotionally unrelated recipient, but the recipient (or the group to which he/she should belong) is specified (e.g. a child)</td>
</tr>
</tbody>
</table>

Indirect donation: when a person donates indirectly to his or her intended recipient  
  i.e. donation to a specified recipient through an exchange programme

<table>
<thead>
<tr>
<th>Unspecified donation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation to an anonymous and unspecified recipient (donating to the waiting list)</td>
</tr>
</tbody>
</table>
Table 2. In total, 331 surveys were sent to transplant professionals in 45 European countries. 113 kidney transplant units from 40 countries and 39 liver transplant units from 24 countries completed the survey. 4 replying centres did not have a living kidney donor programme and 11 replying centres did not have a living liver donor programme, these are marked [bold –]. The replies are grouped into 3 geographical regions i.e. the North-Western, the Mediterranean countries and the Eastern. Bold country = EU-member.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
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<td><strong>Eastern</strong></td>
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<td>Armenia</td>
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<td>[1/1]</td>
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<td>[4/0]</td>
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<tr>
<td>Spain</td>
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<td>Slovakia</td>
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<td>(1)</td>
<td>[1/1–]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>Republic of Macedonia</td>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
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<td>Ukraine</td>
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</tr>
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Table 3. Results from LKD survey divided in three geographical regions in Europe.

<table>
<thead>
<tr>
<th>Living kidney donor programs (N = 109)</th>
<th>North-West N = 62 (%)</th>
<th>Mediterranean N = 15 (%)</th>
<th>East N = 32 (%)</th>
<th>p-value</th>
</tr>
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<tr>
<td>Living kidney donor transplantations</td>
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<tr>
<td>&lt; 25 LKD/year</td>
<td>28 (45)</td>
<td>11 (73)</td>
<td>26 (81)</td>
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</tr>
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<td>Absolute contraindication for LKD</td>
<td></td>
<td></td>
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<tr>
<td>Diabetes type 1</td>
<td>60 (97)</td>
<td>12 (80)</td>
<td>24 (75)</td>
<td>0.045</td>
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<td>Diabetes type 2</td>
<td>48 (77)</td>
<td>11 (73)</td>
<td>19 (59)</td>
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<td>BMI &gt; 40</td>
<td>55 (89)</td>
<td>13 (87)</td>
<td>24 (75)</td>
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<td>39 (63)</td>
<td>9 (60)</td>
<td>14 (44)</td>
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<td>BP &gt; 140/90 mmHg</td>
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<td>2 (13)</td>
<td>7 (22)</td>
<td>0.555</td>
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<td>Well treated hypertension</td>
<td>2 (3)</td>
<td>0 (0)</td>
<td>3 (9)</td>
<td>0.428</td>
</tr>
<tr>
<td>Urine protein &gt; 300mg/24 h</td>
<td>40 (65)</td>
<td>11 (73)</td>
<td>18 (56)</td>
<td>0.527</td>
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<tr>
<td>Surgical techniques</td>
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<td></td>
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<tr>
<td>Open flank incision, rib resection</td>
<td>9 (15)</td>
<td>2 (13)</td>
<td>18 (57)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Laparoscopic techniques</td>
<td>50 (81)</td>
<td>8 (50)</td>
<td>12 (37)</td>
<td>&lt; 0.001</td>
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<tr>
<td>Reimbursement</td>
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<td>3 (20)</td>
<td>6 (19)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Donor follow-up</td>
<td>62 (100)</td>
<td>15 (100)</td>
<td>12 (40)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Donor registries, national level</td>
<td>60 (97)</td>
<td>14 (93)</td>
<td>26 (81)</td>
<td>0.034</td>
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</tbody>
</table>
Table 4 a. Various types of relations accepted between donor and recipient in Europe in centres with living donor programmes, categorised with ELPAT’s classification for living organ donation [14].

<table>
<thead>
<tr>
<th>Who of the following potential donor can donate at your transplant centre?</th>
<th>Kidney donation N = 109 (%)</th>
<th>Liver donation N = 28 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specified donation, direct</strong>&lt;br&gt;Person who donates directly to his or her intended recipient.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td>109 (100)</td>
<td>28 (100)</td>
</tr>
<tr>
<td>Sibling</td>
<td>102 (94)</td>
<td>21 (75)</td>
</tr>
<tr>
<td>Child (adult)</td>
<td>65 (71)</td>
<td>15 (54)</td>
</tr>
<tr>
<td>Grandparent</td>
<td>96 (88)</td>
<td>18 (64)</td>
</tr>
<tr>
<td>Other genetically related family/relative</td>
<td>96 (88)</td>
<td>21 (75)</td>
</tr>
<tr>
<td>Spouse</td>
<td>97 (89)</td>
<td>25 (89)</td>
</tr>
<tr>
<td>Partner</td>
<td>91 (84)</td>
<td>21 (75)</td>
</tr>
<tr>
<td>Other NON genetically related family/relative</td>
<td>74 (68)</td>
<td>14 (50)</td>
</tr>
<tr>
<td>Friend with close emotional relationship to recipient</td>
<td>75 (69)</td>
<td>17 (61)</td>
</tr>
<tr>
<td>An employer or supervisor of recipient</td>
<td>18 (17)</td>
<td>4 (14)</td>
</tr>
<tr>
<td>An employee or supervisee of recipient</td>
<td>18 (17)</td>
<td>3 (11)</td>
</tr>
<tr>
<td>Co-worker</td>
<td>29 (27)</td>
<td>4 (14)</td>
</tr>
<tr>
<td>Acquaintance without close emotional relationship to recipient</td>
<td>23 (21)</td>
<td>4 (14)</td>
</tr>
<tr>
<td>A stranger donating anonymously to a specific recipient e.g. a famous person</td>
<td>1 (1)</td>
<td>3 (11)</td>
</tr>
<tr>
<td>A stranger anonymous to a recipient with defined characteristics e.g. a child</td>
<td>4 (4)</td>
<td>4 (14)</td>
</tr>
<tr>
<td><strong>Specified donation, indirect</strong>&lt;br&gt;Person who donates indirectly to his or her intended recipient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paried exchange “organ swopping”</td>
<td>47 (43)</td>
<td>6 (21)</td>
</tr>
<tr>
<td><strong>Unspecified donation</strong>&lt;br&gt;Donation to an anonymous and unspecified recipient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A stranger anonymous to any recipient</td>
<td>35 (32)</td>
<td>7 (25)</td>
</tr>
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</table>
Table 4 b. Types of relations accepted between donor and recipient for kidney transplantation divided by geographical region and categorised based on ELPAT’s classification for living organ donation [14].

<table>
<thead>
<tr>
<th>Type of relationship accepted</th>
<th>Living kidney donor programs (N = 109)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>North-West N = 62 (%)</td>
<td>Mediterranean N = 15 (%)</td>
</tr>
<tr>
<td>Specified donation, direct</td>
<td>Person who donates directly to his or her intended recipient</td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td>62 (100)</td>
<td>15 (100)</td>
</tr>
<tr>
<td>Sibling</td>
<td>62 (100)</td>
<td>10 (67)</td>
</tr>
<tr>
<td>Child (Adult)</td>
<td>51 (82)</td>
<td>3 (19)</td>
</tr>
<tr>
<td>Grandparent</td>
<td>58 (94)</td>
<td>11 (73)</td>
</tr>
<tr>
<td>Other genetically related</td>
<td>58 (94)</td>
<td>12 (80)</td>
</tr>
<tr>
<td>Spouse</td>
<td>61 (98)</td>
<td>13 (8)</td>
</tr>
<tr>
<td>Partner</td>
<td>61 (98)</td>
<td>14 (93)</td>
</tr>
<tr>
<td>Other NON genetically related family/relative</td>
<td>55 (89)</td>
<td>8 (53)</td>
</tr>
<tr>
<td>Friend with close emotional relationship to recipient</td>
<td>57 (92)</td>
<td>8 (53)</td>
</tr>
<tr>
<td>An employer or supervisor of recipient</td>
<td>27 (44)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>An employee or supervisee of recipient</td>
<td>16 (26)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Co-worker</td>
<td>26 (42)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Acquaintance without close emotional relationship to recipient</td>
<td>21 (34)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>A stranger donating anonymously to a specific recipient e.g. a famous person</td>
<td>1 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>A stranger anonymous to a recipient with defined characteristics e.g. a child</td>
<td>4 (7)</td>
<td>0 (0)</td>
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<td>Specified donation, indirect</td>
<td>Person who donates indirectly to his or her intended recipient</td>
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<td>Pared exchange “organ swopping”</td>
<td>35 (57)</td>
<td>7 (47)</td>
</tr>
<tr>
<td>Unspecified donation</td>
<td>Donation to an anonymous and unspecified recipient</td>
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</tr>
<tr>
<td>A stranger anonymous to any recipient</td>
<td>31 (50)</td>
<td>3 (20)</td>
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</table>
Figure 1. Kidney Transplantations from Living Donors in Europe [1].

Figure 2. Surgical techniques for living donor nephrectomy
Expanding Living Organ Donation in Europe: Attitudes, Barriers and Opportunities. Results from a Multi-country Focus Group Study

Assya Pascalev, Yordanka Krastev, Adelina Ilieva

Bulgarian Center for Bioethics

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Introduction

Living organ donation (hereafter LOD) has emerged as an important source of transplantable organs and a means of alleviating the chronic shortage of organs world-wide. The organs most commonly obtained by LOD are kidneys and segments of the liver but parts of the lungs, pancreas, intestines and even a heart can be transplanted from a living donor\(^1\). LOD produces superior outcomes for the recipient compared to diseased donation [8] resulting in shorter waiting times [6], better recipient and graft survival [22], lower rates of recipient morbidity and mortality [7]\(^2\) and better quality of life [13, 22]. LOD is also shown to be increasingly safe for the donor: the mortality risk for living kidney donors is as low as 0.03% [16] and for living liver donors the risk ranges between 0.2%-0.5% [11, 21]. As a result, many countries have implemented LOD as a medically beneficial, morally justified and legally accepted approach to treating end-stage liver and kidney diseases. Yet, despite its demonstrated advantages, relative safety and legal acceptance of LOD, the rates of LOD in the European Union (EU) remain relatively low: in 2010, only 19.8% of kidney and 3.6% of liver transplants came from living donors [20] and some EU countries have no LOD programs.

The reasons for the low rates of LOD in Europe have not been well understood due to a lack of information about the differences in practices, legislations, policies, attitudes and moral sensibilities concerning LOD in the EU member states. In an effort to bridge this gap in knowledge, as part of EULOD, focus groups discussions (hereafter FGDs) were conducted in four European member states, Belgium, Bulgaria, Estonia and Romania, all of which have low rates of LOD. The goals of the FGDs were to provide insight into the attitudes and perceptions of European transplant professionals and other stakeholders to LOD, and to identify the ethical, legal, financial and practical motivations to perform or not to perform living donor transplantations. The research aimed to facilitate the development of future policies and interventions, which would promote living donation while also protecting the well-being of donors and would address the concerns and needs of transplant professionals. In this chapter, we present in detail the results from the FGDs and, on the basis of these results, we formulate specific recommendations to stimulate LOD in EU.

Methodology

The focus groups were conducted in four EU member states: Belgium, Bulgaria, Estonia and Romania. These countries were selected using the following criteria: low rates of living organ donation, sufficient cultural differences, and representation of both older and new EU member states. One FGD per country was conducted between June and October 2011. Each group consisted of four to six participants, who were health care professionals involved in transplantation (physicians, nurses, transplant coordinators, clinical psychologists), a lawyer with specialty in medical law and members of patient organizations involved in organ donation and transplantation (Bulgaria and Romania). A total of twenty one participants took part in the focus groups, which were facilitated by one or two facilitators each (five in total).

The participants in the FGDs were identified and recruited by a EULOD partner in the country\(^3\). The partners from the studied countries also determined the location of each FGD and conducted

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\(^1\) Living heart donation is rare but possible in limited circumstances, where a recipient of cadaveric lungs receives the donor’s lungs and heart thus making it possible for the recipient to become a living heart donor. A case of living heart transplantation was reported by the New York Times [4].

\(^2\) Patt and Thuluvath estimate the rate of recipient mortality after live lung transplantation to be 12%-14%; however, they caution that it is very hard to draw a direct comparison between recipient survival after lung transplantation from a living donor versus a deceased one because living lung transplantations are performed on patients who “are generally healthier and the surgery is performed electively” [23].

\(^3\) For a list of partners by country, see [12].
the discussion. A uniform FGDs protocol and a list of eight questions for the FGDs were developed in consultation with all partners (see Appendix 1). All potential participants were informed of the purpose of the FGDs and their oral consent was obtained. Participants, who agreed to take part in the FGDs, were contacted via telephone, email or in person and a suitable time for the FGDs was arranged. The duration of FGDs was between 90 and 120 minutes to allow for in-depth exploration of all questions. The FGs was conducted by one or two facilitators, who assisted in the discussion. One facilitator was primarily responsible for asking the questions, while the other acted as a time-keeper, observer, and also took field notes of the discussion. The focus groups were conducted in the participants’ native languages in order to ensure maximum freedom of expression and accuracy of meaning. The only exception was the Belgian FG, which was conducted directly in English. The discussions were audio-recorded and transcribed verbatim. The FG data was de-identified and each participant was assigned a unique coded identifier. The transcripts of the Bulgarian, Estonian and Romanian FGDs were translated into English.

The transcripts of all FGDs were analysed qualitatively using a combination of manual and a software-assisted coding because the combination of these two approaches has been shown to produce more reliable results than each of them alone [33]. An initial cross-coding between the three researchers was performed to ensure coherence of the approach to the interpretation of the data. The first part of the analysis consisted in manual coding where respondents’ answers to each question of the interview were grouped and initially interpreted. It was followed by repeated readings of the remaining focus group transcripts and field notes and the use of memos to capture immediate ideas and impressions. The next step in the analysis involved initial open coding of the de-identified transcripts using the computer assisted qualitative data analysis software NVivo Version 9 (QSR International 2011)4, which is considered one of the most powerful, reliable and user-friendly tools for qualitative data analysis [18, 17]. NVivo helped us to identify concepts and their properties and dimensions by organizing the complex information from the FGDs. NVivo allowed us to navigate the data easily and to make sense of the unstructured information from the transcripts by constant comparison and key words-in-context analyses.

The coding resulted in a total of one hundred and twenty thematic codes, which were grouped into ten broader categories: current practices of LOD, characterizations of LOD, ethical barriers and considerations, reasons for low rates of LOD, legal barriers and considerations, religious issues, financial barriers, attitudes to LOD, other barriers to LOD and transplantation, and strategies to improve LOD. These categories formed the basis for the thematic analysis relative to the scope of the research question. The data was then interpreted in order to understand the overriding concepts individually and in their interactions. Themes and concepts were linked to one another with notes describing the relationships between them. The following main themes were analysed in depth: factors determining views “for” or “against” LOD, reasons for low rates of LOD, barriers to LOD (including legal, religious, ethical, cultural, financial, government related etc.), attitudes of transplant professionals and other stakeholders to LOD, and strategies and opportunities for increasing LOD.

Results

Based on the aims of the study, the following main themes were analysed in depth: factors determining views “for” or “against” LOD, reasons for low rates of LOD, barriers to LOD (including legal, religious, ethical, cultural, financial, government related etc.), attitudes of transplant professionals and other stakeholders to LOD, and strategies and opportunities for improvement of LOD. For each theme, we provide rich quotes illustrating the dimensions of each category and the connections

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4 An overview of NVivo9 is available from the manufacturer [25].
between them. After each quote, in parentheses, we specify the source by participant number and country.

1 Current practices of LOD

The FGDs participants were familiar with a wide range of practices and types of LOD\(^5\). Most frequently, LOD was associated with specified direct donation (where the donor and recipient were either genetically related, i.e., liver donation to a child by a parent) or emotionally related (i.e., a donation between spouses or friends), or specified indirect donation through an exchange program:

“With living organ donation, it is all about an emotional connection.” (P6, Bulgaria)

“The related are blood-related. And then you have the un-related, but emotionally related. But we do not rule out the pure altruistic donor, but so far we haven’t done any.” (P3, Belgium)

Examples of indirect donation to a specified recipient through an exchange program were given in the Bulgarian and Belgian FGDs:

“There are crossed organ donations in the European practice... A couple, a man and a woman, are incompatible between themselves, but they are compatible with another couple and they exchange organs. There are presumptions such as friendship... There are all kinds of ideas worldwide.” (P6, Bulgaria)

The Belgian participants specifically mentioned a recent Living Donor Exchange Program, which was established in Belgium three years ago. The participants noted that the new program had not yet resulted in transplantations due to the lack of a match between donors and recipients.

“We have now, for instance, in Belgium, since I think two years now the Living Donor Exchange Program, which we sort of made in accordance to what is happening for several years in the Netherlands. But so far we haven’t done any transplantation within that program probably because of too low numbers. At the highest point, we had twelve couples, I think, but this didn’t provide a match. And there you can say this is a sort of direct donation of an individual, but it’s without any gain from any part, financial gain or other gain from any of the parties... The kidneys are exchanged between the recipients of the respective donors, because they are compatible or they don’t have any blood group issues.” (P1, Belgium)

Unspecified donation also known as “Samaritan” or “altruistic” donation was mentioned in all four FGDs. It was described as donating to a complete stranger or a waiting list.

“The Netherlands is the only country, which uses the Good Samaritan system... They are the only ones who adopted laws in this sense; in Romania there is no such thing... How is this happening? So the person comes, he is well meant and he says: I want to donate a kidney. I do not care to whom. He is registered on the list, at the

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\(^5\) For conceptual clarity and consistency, throughout this Report, we use the new ELPAT classification of living organ donation [11]. The FGDs participants did not necessarily use the same classification and used terms differently and inconsistently.
moment when a compatible recipient is found, the transplant is performed from the respective donor to the recipient without the donor and recipient knowing each other.” (P1, Romania)

All participants believed that unspecified donation was not practiced in their respective countries.

2 Characterizations of LOD

Overall, LOD was characterized as a special act. The participants described it as “selfless”, “altruistic” and “delicate psychological act”. Most viewed LOD as exceptional and some even viewed it as something abnormal. In the words of a Belgian participant, LOD is a “dramatic” act with possible underlying psychiatric causes:

“Sometimes it’s psychiatric, sometimes it’s less dramatic but it’s a sort of psychological situation or condition, which makes them to decide to do that.” (P1, Belgium)

Unspecified (anonymous) donation was given as an example of a true altruistic act:

“The true altruistic donation, I’m not an expert on that but I do not think that this is really that frequent, and sometimes the altruistic motivation is actually… sometimes you find a different background in these people…” (P1, Belgium)

A Bulgarian participant made a broader observation about the nature of transplantation itself as a special activity that pushes the boundaries of what is humanly possible:

“Transplantation is at the limits of human capacity, at the limits of science.” (P2, Bulgaria)

3 Ethical barriers and considerations in LOD

Ethical considerations figured prominently in the FGDs. The main ethical issues identified by the participants were: informed consent, the right of the donor and the recipient to be free to make decisions about donation and transplantation, the inherent risks of LOD, the moral duty not to harm, and various ethical conflicts for clinicians.

3.1 Informed consent

Informed consent was a major ethical consideration in the FGDs. The participants stressed its importance in LOD both in terms of obtaining clear understanding and proper documentation. Some reasons given for the centrality of informed consent in LOD were:

- the need to ensure the voluntariness of the decision to participate in LOD:
  “No one should be pressured” (P2, Estonia)

- the need to establish trust in the system:
  “There are huge suspicions related to the health care system and to the transplant section in particular” (P1, Romania)
• the need to educate those involved about the complexity of LOD:

“The patient does not know what it is all about” (P6, Bulgaria)

• a strong need to ensure that decisions about LOD are deliberate rather than purely emotional due to the special emotional and/or genetic connection between donor and recipient in LOD:

“Family relations certainly play a role (in declining LOD).” (P2, Estonia)
“It is something that has to form a solid basis because it is clear that to the living donor this is an emotional connection.” (P6, Bulgaria)

• to ascertain legal authorization and to protect providers against liability:

“The main function of the informed consent is to transfer risk. So that it would be deliberate and clear for the patient. This is the case with the donor. If the donor knows the risk, they take the risk. However, if the informed consent did not tell him/her about this risk, this risk remains with the doctor. And that is why it is really important before that... of course, the patient may not want to receive information – they have the right to give up this information, it is done under specific rules.” (P5, Bulgaria)

The Estonian participants pointed out that sometimes the patient would refuse to accept organs from family members:

“But there have been cases where the recipients say they don’t want the kidney. I don’t want my spouse’s kidney. We won’t even determine the blood type, because the person doesn’t want the kidney from the other person. Won’t take it... It’s the person’s moral judgment.” (P4, Estonia)

The Romanian participants believed that, in their country, potential living donors were well informed in advance and had sufficient time to think, discuss and seek advice before deciding whether to donate. In this connection, they mentioned the active role of a specially designated Ethics Committee, which monitors every step in the process of LOD and the subsequent transplantation in Romania.

3.2 Risks and harms of LOD

Two major ethical concerns identified by the participants were the risks involved in LOD, and the potential for harm to the donor. The risks and harm associated with LOD were evoked repeatedly by the discussants in different contexts. The risks and harms were linked to the nature of LOD, to considerations about the well-being of the donor, to the need for robust informed consent, to a perceived conflict with the ethos of medicine, and they were mentioned as a barrier to LOD among professionals and patients.

Some of the participants perceived LOD as inherently contradictory because it requires an otherwise healthy donor to undergo surgery and to accept the risks of the surgery, possible postoperative complications, and in rare cases, negative long-term health consequences.

The participants identified medical as well as non-medical (ethical and psycho-social) risks. The medical risks mentioned in the FGDs were hypertension and, in the case of a kidney donation, the possibility that the remaining kidney could fail rendering the donor in need of dialysis or transplantation:
“Living organ donation is not harmless. The percentage of hypertensive patients among those who have donated a kidney is times as high in 10 years’ time. In another 10 years, hypertension will bring them to heart attacks and strokes, which means that this is not harmless.” (P2, Bulgaria)

“And the risks increase as well, because the one remaining kidney may fail, both kidneys may fail… There are certain risks.” (P1, Estonia)

The participants also identified non-medical risks for the donor such as deciding to donate prior to and without full understanding of the relevant facts, acting irrationally on the basis of emotions (in LOD among related individuals), and being pressured into donation.

The risks and the potential for harm to the donor in LOD were linked to the need to ensure that genuine informed consent for LOD is obtained from the potential donor (see 3.1 above) and to ensure the well-being and safety of living donors. The FGDs participants emphasized that the medical criteria for donor selection must be guided by considerations for the well-being of the donor:

“OK, but these are, again, medical criteria based on which the donors are selected. The idea is that the man… the donor has to be a healthy person, which after the surgery must continue to remain healthy.” (P1, Romania)

### 3.3 LOD, harm and the ethics of medicine

In three of the four FGDs, participants evoked the physician duty not to harm when discussing the ethical aspects of LODs. This duty prohibits physicians from inflicting intentional harm to those in their care. The duty is grounded in the principle of non-maleficence, or Primum non nocere (“above all, do no harm”) [5] p.149. The prohibition against harm is traced to the ancient Hippocratic Oath. It is central to the ethos of medicine and the professional identification of physicians. The FGDs participants repeatedly mentioned the duty not to harm in the discussions of the risks for the donor:

“It makes no sense to make a person ill in order to improve the condition of another one.” (P1, Romania)

“I’ve told everyone this – it’s against all medical principles to help one person and damage the other.” (P1, Estonia)

A Bulgarian participant even went as far as to claim that LOD violates the Hippocratic Oath and makes physicians vulnerable to liability:

“I will tell you right away, the Hippocrates oath forbids living organ donation.” (P2, Bulgaria)

These statements and the underlying sentiments are significant because they point to an internal conflict in some transplant professionals caused by the procurement aspect of LOD. They perceive the non-therapeutic surgery and risks for the donor as a violation of the key prohibition against harm rendering LOD incompatible with the ethos of medicine:

“There the risk is not justified in view of this main therapeutic purpose, which is present with all other medical interventions. Here there is an act of organ donation,
which is not connected to the well-being of the person who performs this act.” (P5, Bulgaria)

Such concerns may act as a powerful barrier against LOD.

3.4 Risks and harm to the donor as barriers to LOD

The risks and harm to the living donor emerged as a major barrier to LOD. In addition to the above mentioned concerns that LOD could violate medical ethics, some participants also noted the increased psychological burden on transplant professionals because, in LOD, they are responsible for the life and health of both the donor and the recipient. A Bulgarian transplant surgeon noted that this leads to a burnout among transplant surgeons. In illustration of these points, a Bulgarian participant shared a moving personal experience with a case of live liver transplantation:

“It is very complicated when you have to bear the brunt. I will tell you about a situation in life. Transplantation to a 7- or 8-month baby with total atresia of the biliary passages, we are speaking of a donor mother who is usually 23-24 years old, it all happens 1-2 years after the wedding. The whole kinsfolk of the girl and the whole kinsfolk of the boy are waiting outside, those are 40 people. You have brought a 22-year old child inside and you have split her open on the table and you are cutting her liver so that you can put it in her 7-month baby. Twenty more cases like that and I quit. We have had enough already, you break down. And this is how it goes worldwide. And the people who taught me this thing, they are also going towards quitting.” (P2, Bulgaria)

The risks for the living donor were identified also as a barrier for patients in need of a transplant because they might not want to receive an organ from loved ones not to expose them to hardship and risks. Participants from the Estonian FGD had cases, where recipients would decline to receive organs from a loved one:

“But there have been cases where the recipients say they don’t want the kidney. I don’t want my spouse’s kidney. We won’t even determine the blood type, because the person doesn’t want the kidney from the other person. Won’t take it.” (P4, Estonia)

3.5 LOD and the duty to help

A participant from the Belgian FGD identified another type of moral conflict. When a transplant professional has to decline a donation by a willing potential donor, who is not a match to the intended recipient, that professional experiences himself or herself as a barrier to the donation. This creates an internal moral conflict for the transplant professional, who is bound by a moral duty to help [5] p.149-152 and p.197-239.

“Maybe one thing is that we are often the barrier to the patient because, to the donor because they want to donate and they are not fit and then there’s... Then we are confronted ethically with someone who really wants to donate an organ.” (P4, Belgium)
The frustration of health providers, who have to decline a potential donor’s offer to donate, is a problem unique to LOD, where providers meet and interact with the living donor and have to consider the interest of the recipient and the interest of the donor.

4 Reasons for low rates of LOD

In all four countries where the FGDs were conducted, the rate of living organ transplantation is low for both kidney and liver [20]. The participants identified a variety of reasons for the low rates of LOD, including: high level of cadaveric donors due to the opt-out legal system and substantial waiting time for a living donor in comparison with the cadaveric one (in Belgium), there was no need for LOD (Estonia), small donor pool due to the small size of the country and small families (Bulgaria and Estonia), lack of government support and inadequate funding for LOD (Bulgaria), and lack of support among older influential professionals (Estonia, Belgium):

“ Well I think we have a rather low level of living donors, kidney donors, is because we have a rather high number of dead donors, cadaveric donors, because of the opting-out system in Belgium.” (P4, Belgium)

“In Bulgaria, families are small and the law permits living organ donation for up to fourth generation of the lateral family branch. And due to the fact that it is a first cousin and the fact that families are small – living organ donation is not in such frequent use.” (P1, Bulgaria)

“The main limitation in Estonia is that we have small families and few relatives.” (P3, Estonia)

In Belgium, attempts were made to increase the rates of LOD, but they did not have significant results:

“We used to do about two living donor kidney transplants a year, but now we’re around ten. But of course we screened a lot more patients, or potential donors.” (P3, Belgium)

“Sometimes we see and screen more donors for one recipient, so the screening goes up, but the operation load does not go up. You only get one kidney each, of course.” (P4, Belgium)

Interestingly, the Romanian participants believed, contrary to the data, that, in Romania, the LOD rates were very high:

“In Romania we probably still have one of the highest rates of… living donors. I mean, at national level... We have approximately 50-60% of transplants performed from living donors. That’s how things really are...” (P5, Romania)

In the Romanian FG, it was noted that the rates of LOD declined when the level of brain dead donors increased in recent years.

The Scandinavian countries and the Netherlands were mentioned by some participants as the most prominent examples of countries with high rates of LOD.
5 Legal barriers to LOD

Overall, the focus groups did not identify legal barriers to LOD. Most of the comments about the transplant laws were positive:

“Well, the law says that it’s, you know, that you can consider living donation in case of emergency, life-threatening emergency. But I think that we have never experienced any legal problems in terms of donation programs or living donation programs or living donation campaigns in terms of the interpretation of the law.” (P1, Belgium)

“We have no legal barriers. Here, living organ donation is limited by a degree of relatedness. It has to be proven… There’s not much for us to discuss. The law is laid down at [sic!] that’s it.” (P1, Estonia)

“Bulgarian law on organ transplants is a modern law, which is absolutely comparable with the laws in the European countries. This is European law. Perhaps it is among the few laws in Bulgaria, which are absolutely comparable.” (P1, Bulgaria)

The Romanian participants mentioned a recent law introduced in 2006 that requires the mandatory assessment of all potential donor-recipient pairs by a designated independent Ethics Committee. Although some Romanian participants characterized the law as restrictive, they didn’t report any negative experiences as a result of it. The only legal barriers to LOD in Bulgaria, Estonia and Romania were the above mentioned restrictions of LOD to individuals, who are related genetically or emotionally. However, the participants did not perceive this restriction as a barrier to LOD. In Romania, the law does not specify to whom one may donate allowing living donation among individuals who are not related in any way.

The existence of an Ethics Committee, which is independent of the professionals involved in the LOD process and transplantations, was identified as an important facilitator of the LOD process in the Belgian and Romanian FGDs.

“Well, there is a good collaboration of the Medical-Ethics Committee so if there is any doubt, or if… there are also very specific guidelines when to contact the Ethical Committee and so if there is any doubt, we can rely on an advice.” (P2, Belgium)

“An Ethics Commission is made up of three members who have no connection with the transplant team: a member, which is representative of the College of Physicians, a psychologist and a member of the clinic where the transplants are performed, which does not have any connection to the transplant team… If one of the three does not agree or has suspicions that there is any kind of reward or gift…, automatically advises against donation of the pair. Only after this Ethics Committee is consulted, the process might go on with the assessment of the pair, with compatibility tests, and so on.” (P5, Romania)

In Bulgaria, there was no independent Ethics Committee for LOD, and the absence of such was mentioned as a barrier to LOD:

“There are always ethical obstacles. There should be a commission, which is completely independent of the people involved in transplantations, and, which is to determine whether a certain living donor is suitable or not. In fact, the donor may give
up the act of organ donation before that commission. This commission is among the places where the living donor may give up and it can say that the waiver is for medical reasons to ensure there is no tension between the donor and the recipient.” (P1, Bulgaria)

6 Religious issues related to LOD

The overall opinion of the participants in the FGDs was that there were no religious barriers to LOD from the various denominations in the four studied countries. The participants acknowledged the positive impact, support and encouragement from some religious leaders to LOD.

“For the general donation, it’s [Catholic Church] in favour.” (P2, Belgium)
“In my opinion, there are no religious obstacles.” (P2, Bulgaria)

As an example for the support of the Eastern Orthodox Church in Romania, a Romanian participant cited a case of a nun who travelled from a monastery to the hospital to donate an organ:

“It was interesting that, after making the donation, she [Orthodox nun] was so impressed, she felt so good, from a spiritual point of view, to a degree that she was willing to donate the organs, which cannot be donated – the liver, this cannot be drawn, at least from an living donor, so she was inspired by a force who told her to continue to donate…” (P2, Romania)

7 Financial barriers to LOD

The FGDs expressed varying views about the extent to which financial coverage of organ donation and transplantation acts as a barrier to LOD in the four countries. Participants in the Belgian and Romanian FGs stated that there were no financial obstacles to LOD. In contrast, the Bulgarian participants deemed the funding of LOD as inadequate:

“Neither the specialists, nor the patients feel good. For the simple reason that the transplantology is not paid in the way that it has to be paid.” (P6, Bulgaria)

The high cost of organ donation and transplantation from living donors was identified as a major barrier in Bulgaria. The participants noted that transplantation from living donors is more expensive because of the pre-donation workup of living donors. This cost was viewed as a major factor contributing to the low rates of LOD in the country.

“Transplantations from a living donor are more expensive, categorically more expensive because the original diagnostics, which has to be performed (they have to be tested all over) makes things more expensive... There is a completely healthy person whom you have to test absolutely all over so that there are no surprises, and it makes things more expensive. Living organ donation is the more expensive transplantation.” (P2, Bulgaria)

“This is the economic part of transplantology. We use the term transplantology because it includes both the operative and postoperative parts, the latter being more problematic in Bulgaria than the transplantation itself.” (P6, Bulgaria)
In the Bulgarian FGD, the financial barriers were viewed as part of a broader systemic problem with the health care system manifested in a lack of governmental support for transplantation and inadequate infrastructure:

“And to us the most serious reason, apart from that with lack of information, is the lack of investments in transplantation programs, in a sense they should not develop in the short run but rather in the long run. There is no such involvement at least at this stage; I hope in the time to come they will prove us wrong.” (P6, Bulgaria)

In the Bulgarian FG, there was a consensus that transplant surgeons were not paid adequately, the equipment was largely antiquated and the transplant centres were not reimbursed promptly and adequately by the state:

“This has long been discussed in the patient community because it is important to us – to the patients. First, it is important to us that our doctors are somehow stimulated.” (P6, Bulgaria)

“This [transplantation] is paid to the hospital and the doctors get reimbursed, possibly, after about a year.” (P4, Bulgaria)

“We [transplant professionals] want payment for our work. I think it is clear to everyone. We want one more thing, for which our ward is especially fighting for. We want equipment and materials, with which we would work at a slightly different level, which will reduce the complications, it will facilitate the work, it will improve the success in many other aspects.” (P4, Bulgaria)

Financial obstacles were mentioned as a barrier to training of transplant professionals and further advancement of LOD in Estonia:

“For us, all the trainings and things are related to finances. A lot of the time, that’s what stops development.” (P1, Estonia)

In contrast, very few financial issues were identified in Romania and Belgium. It was stated that the entire LOD process from pre-donation to transplantation (e.g. screening, hospitalization and follow-up of living donors) had full financial coverage in these two countries. The only financial issues were related to the indirect health costs to donors (in Belgium) or travel expenses to hospital for transplantation (in Romania), which were not reimbursed.

“I think all the costs of the hospital stay are covered by the insurance of the recipient... The screening is reimbursed [multiple speakers] and the follow-up.” (P4, Belgium)

“In the transplant system, the entire intervention, everything in the transplant procedure is reimbursed by the insurance system. So one does not have to pay, [except] for the travel to the hospital and back. That’s all. The rest is all reimbursed.” (P1, Romania)

“So there is no period in which the patients are not covered.” (P4, Romania)
8 Attitudes to LOD

The FGDs explored three types of attitudes to LOD: the attitudes of health professionals to LOD, the attitudes of the public to LOD, and the attitudes of transplant professionals towards LOD among unrelated individuals.

8.1 Transplant and other health professionals’ attitudes to LOD

The FGDs revealed contrasting attitudes towards LOD amongst transplant professionals. The Bulgarian informants believed strongly that transplant professionals and other health professionals have positive attitude to LOD. Generally, LOD is seen as a noble act and Bulgarian doctors do not have objections to it.

“In my modest experience I have not seen a doctor in this field [transplantation] who has a negative attitude. Naturally, with living organ donation one is much more cautious, if I may say so, but the attitude is not negative by any means. This noble act is even more tolerated there… The attitude of the doctor himself is much different because there is a living person from whom you take away an important organ.” (P3, Bulgaria)

Conversely, the Belgian and Estonian focus groups identified a reluctance among some transplant professionals, particularly among older physicians, to endorse LOD. This was attributed to a lack of tradition, lack of awareness and lack of donor follow-up after donation:

“I think lack of tradition creates lack of awareness. Also we see it in our assistants so the nephrologists in training who become nephrologists in regional centers and who have been involved with the living donation program, they know the program, they know how patients are screened, how recipients are doing afterwards and they are in favour, and they begin to discuss. Once you are not involved in it you do not see it, there’s, you remain reluctant.” (P4, Belgium)

“I think historically there is reluctance amongst the health professionals to harm a healthy body and to consider living donation.” (P3, Belgium)

“I know that there’s a doctor who is strictly opposed to that [living donation of liver]. I also know there’s a doctor in [town in Estonia] opposed to the idea, and because of that doctor, quite a few transplantations haven’t taken place. They won’t agree to do it [liver transplantation from living donor], they don’t want to mess around with things like that.” (P1, Estonia)

8.2 Public attitudes to LOD

The FGDs revealed the absence of public debate on the issue of LOD. In addition to the lack of definitive public attitudes towards LOD, ambivalent and even conservative attitudes were reported by the participants. It was noted that, in Belgium, a more conservative attitude could be found even among some young people, including medical students.
“I have the impression that there is still also some public mentality or input, which differs, I have the impression, in Belgium, from the surrounding countries. Maybe it’s the awareness or the fact that in all these previous years the elder colleagues have not promoted living donation, but it’s also, I think, less present in the public domain.” (P2, Belgium)

“Another possible reason is that there has been a culture not pro – I’m not saying against, but not pro – living donation, and it takes time for the newer generation to bear in mind, or to think about living donation.” (P2, Belgium)

“Surprisingly if you ask students now how they are looking towards living donation, then your intuition would say well, of course the younger people are all in favour, but that’s not the case.” (P1, Belgium)

The absence of an explicit public stance on LOD was attributed to a lack of public awareness, a lack of sufficient information among ordinary people, specialists and potential donors, insufficient promotion of LOD by transplant professionals, a received culture of “not pro” LOD, and insufficient presence of the issues of LOD in the public domain. A patient representative from Bulgaria suggested that the lack of adequate public support for LOD could be explained by insufficient moral rectitude among the public:

“From patients’ perspective – we have said it more than once. The problem with organ donation as a whole exists in Bulgaria because Bulgarian psychology is not at the level, at which it should be.” (P6, Bulgaria)

8.3 Attitudes towards LOD among unrelated individuals

The expression “LOD among unrelated individuals” refers to LOD in the absence of a legally recognized relation between the donor and the recipient such as a genetic or emotional relation. This type of LOD is commonly referred to as “anonymous”, “altruistic” or “Good Samaritan” donation, where a person donates an organ to a stranger. This type of LOD remains highly controversial because it is hard to justify from the donor’s perspective. The motivation of the donor appears suspicious, there is potential for coercion and exploitation of potential donors and there are risks of commodification and organ trafficking. As a result, very few European countries allow LOD among unrelated persons. Most EU countries restrict LOD to related individuals, although the national legislations use different criteria for relatedness and allow certain exceptions.

Most transplant professionals and other participants expressed their strong views against LOD to an anonymous recipient, e.g., donating to strangers on the waiting list (unspecified donation). The main reason against such a donation was that it can lead to organ trade:

“This [donation to unrelated people] is a prerequisite for trade of organs. The emotional relationship is not the most appropriate solution – there should be a genetic relation.” (P1, Bulgaria)

In the Bulgarian FGD, the attitudes towards unrelated (unspecified) donation were somewhat positive only if the donation were to be made to the waiting list. However, doubts were expressed

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6 For a critical analysis of the use of “altruistic”, “Good Samaritan” and “unrelated donation”, see ELPAT’s new classification for living organ donation in [11].
about the objectivity and equity of the allocation of the organs and about the overall integrity of the system. The public attitudes towards unrelated (unspecified) donation were also discussed. The common sentiment was that the public was not ready to support donation to an anonymous person:

“Here [in Estonia] people don’t donate to complete strangers. At least I’m not aware of any cases like that.” (P2, Estonia)

“Nobody in this society says, “I will donate my organ to a stranger.” There is no such thing. From what I have seen, it happens either because it deals with a very close kin or a family relation. I have not seen transplantation by an anonymous person.” (P2, Bulgaria)

“No. For example, our people, the Romanians, they would rather sell their kidneys, instead of donating them. And so it happens that a transplant can be performed in Romania from a living donor only if the recipient comes with his own donor… So, we used to have people coming to the office and saying: „well, I want to donate a kidney“. Obviously, the question is: „and how do you think to donate it?“ „Well“, he says, „You see, Doctor, I have some issues, I took a loan from the bank, and I could not pay back, and I took some money from money lenders and the money lenders are going to kill me – that’s the system in Romania.“ (P1, Romania)

Although Belgium was among the few EU states, which allows LOD to a complete stranger, according to the Belgian participants, such a donation had not been performed yet:

“We do not rule out the pure altruistic donor, but so far we haven’t done any.” (P3 (Belgium)

9 Other barriers: Donor support and compensation

There was a wide agreement among participants that donors should be supported by society and should receive some type of social guarantees for the act of donation:

“Talking about living donors, right? They could have some social guarantees.” (P1, Estonia)

All participants endorsed social guarantees to living donors such as free, continuous medical care and medical leave. There was also an agreement that donors should be given a high priority on the waiting list in case they develop insufficiency and need transplantation.

On the question of donor compensation, the participants were more ambivalent. Some thought that donors must be compensated while others disagreed:

“I imagine there could be something.” (P2, Estonia)

“I think that donation should be a completely selfless act.” (P1, Bulgaria)

A distinction was drawn between remuneration (a payment made for buying an organ) and compensation. While some deemed compensation acceptable, remuneration was viewed negatively by the participants:
“With remuneration, there is the nature of payment and it is as if you buy the organ yourself. And the compensation is always given as compensation for damages.” (P5, Bulgaria)

“He [the donor] cannot receive any type of material benefit, or of any other nature. The law 95, in Title VI, specifically mentions this.” (P1, Romania)

“I don’t think that it will make a whole lot of difference in a rich country like Belgium. And secondly, well, I always have doubts that maybe the very poor, like they say the fourth world, in our country, will maybe then go for a quick gain. I’m not sure, but that’s always the risk.” (P4, Belgium)

There was a strong sentiment that donors should be protected against discrimination and should not be excluded from benefits such as life insurance or bank loans because a person who donated would have better life expectancy than the average client of the insurance companies. Two of the focus groups (Belgian and Estonian) provided examples of occasions when donors have been denied bank loans or life insurance.

The problem with the social integration of living donors after they donate was discussed in the Bulgarian and Estonian FGDs. Some participants were concerned about possible employment discrimination against donors because of employer perception that donors were “future sick people”.

10 Strategies and opportunities to increase and improve LOD

In the course of the FGDs, the participants identified a number of concrete strategies and opportunities for improving LOD in their respective country. The proposed measures reflected the specific needs and circumstances of each country with some of the proposals overlapping across FGDs. Thus, the Belgian, Estonian and Bulgarian participants stressed the importance of raising awareness about LOD amongst the general public through education. The role of the media in this process was given as an example in Belgian FG:

“Well, you have the government, which makes those announcements of public interest. But you might put it in another form or another format. But maybe the message about living donation and the safety of it and the results of it should be more, make it in plain language and in a very easy way to absorb.” (P1, Belgium)

The need to improve the education of health professionals concerning LOD was mentioned in the Estonian and Belgian FGs.

Participants in the Bulgarian and Estonian FGs suggested strategies to remove the financial barriers to LOD and transplantation. Among them were: giving donors a priority on the waiting list if they need a transplant, and providing them with all necessary support after the donation:

“A donor would be on top of the waiting list if he/she needed a transplant. How many donors have we had who needed a transplantation themselves?” (P2, Estonia)

Participants in the Belgian and Estonian FGDs proposed to create national and international registries of LOD in order to collect data on the long-term outcomes from LOD. It was suggested that the registries should collect information about the outcomes for both the recipient and the donor, about regular check-ups of donors and about complications. Subsequently, this data could be used to publicize the safety and benefits of LOD among health professionals and the public at large:
“There are more and more registries from other countries that are convincing that these patients [donors] fare well, that the outcome is good as far as remaining kidney function, hypertension, and also the vital organs is quite good.” (P4, Belgium)

In this connection, the importance of the long-term follow-up of donors was stressed in the Belgian FGD:

“Well we can tell you that in our hospital we follow the guidelines from Amsterdam according to living donation, and here in the pre-donation work-up, the potential candidate who wants to donate is being said “Listen, we would like, if you will be operated we expect you to be on a long-term follow-up.” (P2, Belgium)

The Romanian participants did not think that there was a need to increase LOD. On the contrary, a Romanian participant (P1) suggested that their priority should be reducing the rate of LOD and increasing the donations from brain dead donors.

Discussion

Major findings

Our study of the attitudes and perceptions of European transplant professionals, lawyers and patient representatives shows the existence of some similarities, but also significant differences on the issue of LOD. A summary of the main points, which emerged from the FGDs is presented in Table 1.

The key differences amongst the countries concern the presence or absence of financial barriers, differences in the legal requirements about unrelated (specified and unspecified) donation, issues related to the level of social protections and compensation for donors, and certain ethical issues. The remaining themes reflect differences due to cultural and geographical specifics or differences related to the national health systems.

Ethical considerations figured prominently in the FGDs with participants giving highest priority to informed consent and the well-being of the living donor. The medical and psycho-social risks for the donor presented ethical and legal challenges, which were identified as barriers to LOD. Among the ethical issues identified in the FGDs, two are unique to LOD: the concern about the inevitable physical harm to the donor and the internal conflict when clinicians see themselves as a barrier to donors who wish to donate, but cannot due to health reasons. In both instances, the practice of LOD requires that transplant professionals make hard choices weighing the interest of the donor against those of the recipient.

We found that religion and the law were not perceived as barriers to LOD, with the exception of unrelated donation, which was allowed in Belgium. Both transplant professionals and the public were believed to have a negative attitude to this form of LOD and to paid donation. On the other hand, transplant professionals had a positive and supportive attitude towards LOD among related individuals.

As barriers to LOD participants listed a lack of awareness among health professionals and the general public, lack of support by some influential health professionals, and lack of registries for documenting the long-term benefits of LOD. Financial barriers played a role in the three newer EU member states but were not present in Belgium. Likewise, the newer member states reported that systemic problems in the functioning of the health care system and broader economic factors impeded the development of LOD. Participants in the Bulgarian and Belgian FGDs reported cases of discrimination against donors by employers and banks. There was a perceived need and great appreciation among all participants for procedural fairness in LOD in the form of independent ethics.
committees and robust informed consent processes. The discussions also highlighted certain needs of transplant professionals, such as addressing professional burnout, access to adequate equipment and work conditions, and access to follow-up data concerning the long-term outcomes of transplantation.

The results from the FGDs point to a multitude of factors related to the low rates of LOD in the studied countries including economic, demographic, moral, political and cultural factors. They need to be addressed by an equally broad range of actions tailored to the specific needs of each country.

**Strengths and limitations of the study**

To our knowledge, this is the first multi-country study of attitudes and barriers to LOD in EU countries, where LOD is legal but its rates are very low. The study includes both old and new EU member states characterized by very different religious, cultural, historic and economic realities. An additional strength of the study is that it pays special attention to such contentious issues as unrelated LOD and donor compensation.

This study has several methodological limitations. The first limitation was linguistic: the FGs were conducted in the participants' native language to allow maximum freedom and accuracy of expression with the exception of the Belgian FGD, which was conducted in English. The translations to English might have caused some loss of meaning. Wherever we anticipate a possible loss of meaning, we verified the data with the help of the FGDs moderators, who were native speakers and EULOD partners.

Secondly, each FGD was led by different moderators. This might have resulted in different moderation styles and different emphasis on the various themes in the FGDs. We made an effort to mitigate the differences by providing the moderators with detailed instructions and a uniform FGD protocol.

A further limitation to our study was the heterogeneous profile of the FGDs. While the Belgian and Estonian FGs included participants from a single transplant centre, the Bulgarian and Romanian groups included other stakeholders and professionals from multiple centers. This might have affected the range of expressed views because professionals from a centre may share a distinct institutional culture different from the culture of professionals from another centre in that country.

Finally, it should be noted that although our study aimed to understand the factors affecting LOD in the four countries, the results reflect the perceptions of the participants about LOD in their countries as opposed to how things actually are. Still, these perceptions offer important information about LOD because the latter is a complex phenomenon, which depends on the attitudes, perceptions, and trust of all stakeholders.

**Recommendations**

Based on the attitudes and barriers to LOD, identified by the various stakeholders in the FGDs, and in light of their suggestions for improvement, we reach the following recommendations for increasing LOD in these countries:

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.

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, which 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.
Conclusion

The results of the EULOD FG 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 sheds light on the attitudes of transplant professionals and other stakeholders to LOD and on their concerns and needs. The results from the FGDs point to a multitude of factors contributing to the low rates of LOD in these countries including economic, demographic, moral, political and cultural factors. The variety of barriers suggests that efforts to improve LOD should be equally broad and country-specific. We hope that this information will stimulate further research and will help researchers and policy makers to develop strategies for overcoming the obstacles and to increase LOD in EU. The complexities of LOD, which surfaced throughout the study, are likely to have broader relevance for the future of LOD in Europe reminding us yet again that “transplantation is at the limits of human capacity, at the limits of science.” (P2, Bulgaria)

Authors contributions

Assya Pascalev participated in the research design, performed the research, participated in the data analysis and wrote the manuscript. Yordanka Krastev participated in the research design, data collection and analysis, and wrote the manuscript. Adelina Ilieva participated in the research design, data collection and analysis, and read and approved the manuscript.

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Bibliography


Table 1: Four-country comparison of LOD issues: summary

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<th>Theme</th>
<th>Belgium</th>
<th>Bulgaria</th>
<th>Estonia</th>
<th>Romania</th>
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</thead>
<tbody>
<tr>
<td><strong>Reasons for low/high rate of LOD</strong></td>
<td>High level of cadaveric donors due to opt-out system; substantial waiting time for living donor</td>
<td>Small families; lack of government support and financial barriers</td>
<td>Small families</td>
<td>Need for high transplant activity; living donors compensated for the absence of brain dead donors.</td>
</tr>
<tr>
<td><strong>Legal barriers</strong></td>
<td>No legal barriers.</td>
<td>No legal barriers.</td>
<td>No legal barriers.</td>
<td>Law restricts donation only to first degree relatives. In place since 2006 after couple of cases of organ trafficking.</td>
</tr>
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<td></td>
<td>Very modern and balanced low; gives freedom of donation between genetically or emotionally related people, including civil unions and adoptees. Excludes unrelated and strangers; lack of team work between transplant professionals and lawyers.</td>
<td>Allows donation from both genetically and emotionally related people; no cases of donation of unrelated people.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethical and moral barriers</strong></td>
<td>When doctors see themselves as a barrier to donors who want to donate but cannot due to medical reasons and the fear of causing donors disappointment and frustration. Ethics Committee as facilitator to LOD.</td>
<td>Lack of independent Ethics Committee. Difference between risk and doctor’s mistake. Role of informed consent and the right of the potential donor to receive or not receive the information about risk of LOD.</td>
<td>Donor’s right to donate free from any pressure and recipient’s right to accept or refuse an organ.</td>
<td>There is independent Ethics Committee that assesses each donor-recipient pair and provides its final opinion after total consensus is reached. Importance of being independent from transplant team.</td>
</tr>
<tr>
<td><strong>Religious reasons</strong></td>
<td>No religious barriers. Catholic Church is in favour of general donation.</td>
<td>No religious barriers. the Church doesn’t play a role. Muslim and Roma minorities are in favor, Catholic church and Orthodox Patriarch support, National church has not issued an official position</td>
<td>No religious barriers. The nation is not very religious.</td>
<td>No religious barriers, the Church plays an important role in supporting transplantations.</td>
</tr>
<tr>
<td><strong>Financial barriers</strong></td>
<td>No financial barriers. There is full financial coverage for the whole LOD process from pre-donation to transplantation (e.g. screening, hospitalization and follow-up of living donors). Indirect health costs to donors are not reimbursed.</td>
<td>Yes: financial barrier seen as crucial to LOD. Transplantations from living donors are more expensive compared to deceased donor transplantations. Lack of financial support for hospitals performing LOD and transplantation.</td>
<td>No major barrier. Only financial obstacles for training of transplant professionals and further advancement of LOD.</td>
<td>No financial barriers. Full financial coverage of process by health insurance. The only expense not covered is the expenses for travel to the hospital for transplantation.</td>
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<tr>
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<td>Estonia</td>
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<tr>
<td>Other barriers</td>
<td>Possibility for exclusion of donors from life insurance or bank loans.</td>
<td>Lack of government commitment and investment in transplantation programs. Lack of integration of donors after the donation. Employment discrimination of recipients.</td>
<td>No guarantee for medical insurance to cover quality of life issues of the donors.</td>
<td>Medical limitations, e.g., lack of suitability due to hypertension or other disease of the donor.</td>
</tr>
<tr>
<td>Attitudes to LOD among health care professionals</td>
<td>Culture of “not pro – living donation” amongst some doctors; conservative and restrictive attitudes; some young people are reluctant or have certain threshold to LOD.</td>
<td>Positive despite low public awareness; for compensation and against remuneration of donors.</td>
<td>Reluctance to LOD of liver and lungs in some doctors.</td>
<td>Positive. There is a pressure for increasing cadaveric donations.</td>
</tr>
<tr>
<td>Donation to people on the waiting list (unspecified donation)</td>
<td>Not mentioned. There is a special Living Donor Exchange Program to support indirect donation to a specified recipient through exchange program (indirect donation).</td>
<td>Both for and against. Against – can be a step towards trade of organs. For – doubts about the subjectivity and equity in the allocation of the organ and distrust in the system.</td>
<td>Does not exist; public attitudes against donation to “complete strangers”.</td>
<td>Against - Romanians would rather sell their kidneys, instead of donating them to a stranger.</td>
</tr>
<tr>
<td>Compensation for the donor</td>
<td>Follow-up of donors; use of hospital services.</td>
<td>Donors can use hospital services years after the donation.</td>
<td>No compensation for donors.</td>
<td>Donors receive medical insurance and can use hospital services.</td>
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<tr>
<td>Improved LOD</td>
<td>More education for health professionals; raising public awareness by delivering the message in plain language; national and international registers to investigate long-term outcomes from LOD.</td>
<td>Removal of financial barriers to LOD and transplantation, giving donors a priority on the waiting list if they need a transplant; social, emotional support and better integration of people after the donation.</td>
<td>Giving donors a priority on the waiting list if they need a transplant; psychological support and social guarantees for donors; national register for LOD; membership in Eurotransplant.</td>
<td>Opposite: Romania should decrease LOD and increase brain dead donors</td>
</tr>
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Appendix 1: Questions for the Focus group discussions

1. Why is the rate of living donation in our country so low?

2. What are the main barriers to living donation? Discuss all of these:
   a. are there any **legal barriers** and restrictions?
      - What are they? Are they justified?
      - How can they be removed?
   b. are there any **ethical and moral barriers**?
      - What are they?
      - Are they justified?
   c. are there **financial barriers**?
      - What are they?
      - How can they be removed?
   d. are there any **religious reasons** not to perform living donation?
      - What are they?
   e. are there any **negative attitudes** to living donation among **health care professionals**?
      - What are they?
      - Are they justified?
      - How can they be changed
   f. can you think of any other barriers not yet discussed, e.g., institutional barriers?

3. Should people be allowed to donate an organ to someone with whom they are NOT related genetically or emotionally, but whom they choose to help (e.g. the donor has a sister who dies of renal failure and now she wants to donate a kidney to be used to save the life of someone with kidney failure)?
   a. Why or why not?

4. Should people be allowed to make a general living organ donation without specifying to whom it should go and without knowing the recipient, e.g. donating an organ to the (local, national, international) waiting list?
   a. Why or why not?
   b. Does the distance (local, national or international waiting list) make a difference?

5. Should there be any restrictions on living donation regarding:
   a. Who can donate?
   b. To whom one can donate (relative, stranger)?
   c. Should younger people donate to older recipients?

6. Should there be some compensation for the donor?
7. What kind of compensation, if any, will be morally permissible? Examples:
   - guaranteed top spot for transplantation if the donor needs an organ in the future
   - covered medical expenses in case of post-operative complications
   - covered living expenses in case of temporary disability post-donation
   - paying life insurance coverage for the donor
   - monetary compensation

8. How can living donation be improved?
Ethical Analysis of the Arguments for and against Living Organ Donation

Assya Pascalev, Yordanka Krastev, Adelina Ilieva

Bulgarian Center for Bioethics

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Introduction

Part II of WP2 aims to analyse the normative aspects of living organ donation (hereafter LOD). It accomplishes this on 2 levels:

(1) via empirical research of the actual lived attitudes of medical professionals towards LOD presented in Deliverable 5 titled “Expanding Living Organ Donation in Europe: Attitudes, Barriers and Opportunities. Results from Focus Groups Conducted in Four European Countries” and

(2) via theoretical, normative analysis of the ethical reasoning behind the various arguments to perform or not to preform LOD, presented here (Deliverable 5-B). The primary focus of the analysis is the moral justifications for or against LOD. The aim is to assess these justifications and to develop ethical arguments in support of living organ donation. These arguments could serve to inform policy recommendations and revisions of professional codes of ethics.

Deliverable 5-B presents the results of the analysis of the moral justifications for or against LOD. The Deliverable has the following structure: Firstly, we present the methodology of the ethical analysis. Secondly, we summarize the ethical concerns identified in the Focus Groups analysis in previous Deliverable 5-A. Thirdly, we summarize the main arguments for and against LOD. Fourthly, we offer an in-depth analysis of the major moral concerns raised by LOD. Finally, we present the concrete implications of the ethical analysis for the practice of LOD.

The ethics of organ donation from living donors has been the subject of heated debates ever since the practice became a reality in 1954 with the first living kidney transplantation between identical twins [33, pp. 3259-3264]. In the intervening decades, numerous successful transplantations have been performed using organs from living donors; the safety of LOD for both the donor and recipient has improved substantially [15: p. 242; see also 33; 38: pp. 24-30] and the medical and socio-economic advantages of LOD have been well demonstrated [29: p. 123]. Yet, the practice remains morally controversial and fairly restricted in scope resulting in missed opportunities to help patients in need and to alleviate the shortage of organs. The serious consequences of banning or restricting LOD on moral, legal, cultural or other non-medical grounds become an ethical issue of its own. This raises the question whether the moral reservations to LOD and its legal restrictions are ethically justified and how to determine the boundaries of morally permissible LOD. In this chapter, we offer a critical analysis of the major ethical arguments regarding LOD in order to assess the morality of LOD with a focus on the implications of these arguments for medical ethics and the physician-patient relationship. The conclusions of the ethical analysis of LOD would have implications also about the laws and policies governing LOD and for the ethos of transplant professionals because these laws, policies and professional norms rest on the ethical concepts, values, and principles discussed and tested here. It is beyond the scope of this chapter to spell out the specific implications of the ethical conclusions for concrete laws and policies on LOD. Nonetheless, we hope that the insights and conclusions reached here will identify important ethical considerations, which should be part of a general framework for evaluating laws, policies and individual actions concerning LOD.

Our analysis leads to the following conclusions: LOD is morally justified on the basis of donor autonomy and to some degree on grounds of beneficence. Consequently, the moral permissibility of LOD is limited to autonomous donors and cannot be justifiably extended to minors and other incompetent persons. They lack of autonomy and thus the autonomy-based justification of LOD does not apply.

As noted in the previous Deliverable, only a fraction of the liver and kidney transplantations in Europe use living donors, some European countries do not develop LOD and those who do practice LOD often face numerous legal restrictions as to who can become a living donor often limiting LOD to individuals who are related genetically or emotionally.

The analysis of the ethical arguments utilizes a classification of normative arguments for and against LOD developed in collaboration with Mihaela Frunza (SACRI) and Leonie Lopp, Bijan Fateh-Moghadam, and Thomas Gutmann (Centre for Advanced Study in Bioethics at the University of Münster) in May 2011.
not apply to them. We draw a distinction between what is medically optimal and what is optimal all things considered and conclude that LOD is not the morally preferable alternative and should be subsidiary to other therapies such as organs generated thru stem cell (molding) and deceased donation. We also argue that, unless we are prepared to accept a paid market for organs, LOD to strangers cannot be morally justified. The moral principle of justice requires LOD to involve some form of benefit to the donor in compensation for the burdens (risks, harms, pain and discomfort) associated with the donation. These benefits should be defined by the donor, and may be broad enough to include psycho-social and moral benefits such as increased self-esteem and the positive feeling of helping another. When applied to LOD among strangers, however, the psycho-social benefits may be too weak to justify the burden of donation. This makes it necessary to provide other types of compensation, including monetary exchange as a universal method of compensation. However, monetary compensation for organs is morally repugnant for the number of reasons stated in the literature against organ sales. Therefore, LOD to strangers in the absence of clearly identifiable benefits to the donor cannot be morally justified. For the most part, our conclusion largely supports current position of the Oviedo Convention on Organ and tissue removal from living donors for transplantation purposes (of the Chapter VI). Article 19 – General rule states that “1. The removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness. 2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.” We also concur with Article 20 on the protection of persons unable to consent to organ removal, which states that “1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.”

**Methodology**

The analysis of the normative arguments for and against LOD proceeds in 5 steps:

1. a literature review to identify normative arguments concerning LOD;
2. developing a typology of the normative arguments;
3. developing the theoretical framework of our analysis of the arguments;
4. assessing the central arguments with the help of the ethical framework;
5. developing conclusions and recommendations resulting from the normative analysis.

**1 Literature review to identify normative arguments concerning LOD**

Literature reviews in ethics have a different purpose than literature reviews in other disciplines in that ethics literature reviews are not aimed at providing qualitative data on the basis of which one can draw ethical conclusions. This is because ethical justification is not a matter of empirical data and facts play only a limited role in the analysis of what is morally right or wrong. Ethics is a normative, action-guiding discipline, which does not aim to reveal matters of fact such as how things are or have been but matters of values to guide our conduct such as how things ought to be. As famously noted by prominent British philosopher David Hume, normative (moral) conclusions about how things ought to be is an ethical speaking cannot be derived by factual premises about how things are (the ought-is gap) [30, Book III, Part I, Section I]. Therefore, ethical justification is not measured by the number of arguments or articles for or against a particular position because ethical correctness is neither a matter of opinion, nor is it determined by a majority vote. Ethical correctness is a matter of logical soundness and moral justification, which takes into account the relevant facts and uses the methods of philosophical inquiry. Consequently, the aim of a literature
review in ethics is to provide a comprehensive view of the range of arguments on a given topic, the evolution of moral perspectives and the patterns of moral reasoning used to assess the moral quality of the topic at hand.

The aim of the literature review of normative arguments for and against LOD was to provide an overview of the various types of arguments in order to identify patterns of moral reasoning for and against LOD and to subject them to an ethical analysis. We conducted a search in the two largest publicly available databases PubMed, the database of the US National Library of Medicine contains 253,000 citations in bioethics and ETHXWeb (including the Islamic Ethics Databases) of the Kennedy Institute of Bioethics at the Georgetown University. The Bioethics Research Library (BRL) databases of the Kennedy Institute of Bioethics currently hold 310,000 bioethics citations including books, book chapters, journal articles and laws. A detailed description of the search strategy is provided in Appendix-1.

The ETHXWeb research strategy was adapted to the specific hierarchy and selection of terms and of key terms at BRL. For instance, every single item is already screened to be of “bioethics” nature, so filtering out of medicine-specific topics, such as immunosuppressant drugs is not necessary.

The search strategy calls for grouping the research by legal, theoretical bioethics and applied bioethics. The analysis demonstrated that these categories approximately relate to existing subject categories at BRL as demonstrated in the following table:

<table>
<thead>
<tr>
<th>Search Strategy Terms</th>
<th>Corresponding BRL Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approach</strong></td>
<td></td>
</tr>
<tr>
<td>Legal</td>
<td>Legal</td>
</tr>
<tr>
<td>Bioethics Theory</td>
<td>Philosophical, Analytical, Case Studies</td>
</tr>
<tr>
<td>Bioethics Applied</td>
<td>Religious, Empirical</td>
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<tr>
<td><strong>Source</strong></td>
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<tr>
<td>Research</td>
<td>Journals</td>
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<tr>
<td>Gray</td>
<td>Books, Manuals</td>
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<tr>
<td>Review</td>
<td>Review</td>
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</table>

The juxtaposition of Approach and Source yielded eighteen distinct groups of search results, achievable by executing the Boolean searches below. In order to replicate the results, the researcher needs to copy and paste strategies into search box for Boolean Search: http://bioethics.georgetown.edu/databases/ethxweb/ethxbool/index.html

Additionally, the required data range (1/1/1990-present) should be applied as criteria in each individual strategy. The language selection requirement was to limit the research to the official languages of EU (and Russian). The language selection should be applied as criteria in each individual strategy. All languages in the dropdown list need to be selected, except Japanese, Other (Chinese, Hebrew, and Afrikaans citations) and Serbian. In order to format the results to desired specifications, put ‘Display per Page’ at MAX (bottom of the search page).

The PubMed search strategy was also adopted to adhere to the taxonomy and key terms of the PubMed databases. For instance, the PubMed database references all journals. Hence, the search for journal and review articles will be conducted in PubMed http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed.
These searches resulted in over 2800 titles on organ donation and transplantation published between January 1990 and October 2010 in English and other European languages. The results were organized in a table specifically designated for ranking of the sources for their relevance to the normative aspects of LOD. The most relevant titles were used by BCB and WWUM to develop a table (map) of arguments referenced here and presented in detail in Deliverable 6. To avoid unnecessary duplication, below we only briefly summarise the resulting classification of arguments. For a detailed account, we refer the reader to Deliverable 6 by Leonie Lopp (WWUM).

2 A typology of the normative arguments

The typology of ethical arguments presented in this section utilizes a classification of normative (ethical, legal and policy) arguments against LOD developed by the authors in collaboration with Thomas Gutmann, Bijan Fateh-Moghadam and Leonie Lopp (Centre for Advanced Study in Bioethics at the University of Münster) and Mihaela Frunza (SACRI) as part of the EULOD project. The detailed classification of the resulting map of arguments has been presented in Deliverable No. 2 (DOW: 6 of 13) developed by Leonie Lopp, who also offers a legal analysis of the arguments. Since ethics is different from law in its purpose, objectives, standards, modes of reasoning and justification, some of the conclusions of the ethical analysis presented here differ from certain conclusions of the legal analysis in Deliverables 6 and 7. The main types of arguments, however, are the same.

The variety of complex moral arguments on LOD can be grouped in two categories: (1) arguments about the morality of LOD per se and (2) arguments about the moral boundaries of LOD such as its scope and scale.

The first group of arguments centers on the harm to the donor, the donor's autonomy and Informed consent as sufficient to negate the harm, and on whether genuine informed consent for LOD could be ever achieved and ascertained [46: pp. 1148-1153], and if so, whether donor consent is sufficient to justify the physical harm of organ removal from the donor [20: pp. 91-96]. Other arguments examine the morality of LOD on consequentialist grounds weighing its benefits against such possible negative consequences of LOD as the potential for abuse, undue pressure [8] and exploitation of potential donors [51], the commodification of the human body [45: pp. 1847-1937; 56: p. 114], the emergence of human trafficking for transplantation and/or commercialization of LOD and concerns about the equitable access to transplantable organs by those in need. Such consequentialist arguments tend not to be conclusive or particularly philosophically interesting in that their soundness depends heavily on empirical research as to whether the projected negative consequences actually obtain in practice and whether appropriate safeguards can be implemented to prevent the negative consequences from occurring.

The second group of arguments concerning LOD examines the moral boundaries of LOD such as its scope and scale. Such arguments reflect the ever growing need of transplantable organs, the advancements in immunosuppression therapies and the recent expansion of LOD to include broader categories of potential living donors. The ethical concerns here revolve around the moral permissibility of specific types of LOD such as cross-over LOD [1: p. 152], unbalanced paired exchanges, living paired cascade exchanges and unspecified LOD to a stranger or to the waiting list. Included in this group are also arguments about who could become a living donor, what constitutes a morally permissible relationship between a donor and recipient (e.g., should LOD between complete “altruistic strangers” be allowed [17]), whether certain vulnerable individuals such as children

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3 For an explanation of the terminology used to describe the various types of LOD, see Dor, F. Massey, E. Frunza, M. Johnson, R. Lennerling, A. Lovén, C. Mamode, N. Pascalev, A. Sterckx, S. Van Assche, K. Zuidema, W. Weimar, W., New Classification of ELPAT For Living Organ Donation, 2011 Transplantation.

4 A definition of the different types of LOD and an overview of the various ethical and policy issues posed by them can be found in Lainie Friedman Ross [48]: 151-172.
and mentally handicapped persons should be living donors, how should organs from living donors be allocated and what specific systems of allocation should be used.

While the second group of arguments address important and challenging ethical issues, answering such concerns depends critically on whether or not the very practice of LOD can be morally justified. Therefore, the fundamental ethical question is whether or not LOD is morally permissible. It precedes questions about the morality of any specific type of LOD and is the focus of this analysis. In this Deliverable, we focus on the first group of arguments concerning the moral permissibility of LOD as such and discuss arguments of the second type only briefly as applications of the general arguments. In the process, we also hope to shed light on certain conceptual and logical confusions, which have plagued the debates on the morality of LOD. The conclusions of this analysis have direct implications for bioethics, and for the law and policies related to LOD.

3 The theoretical framework of the ethical analysis of the morality of LOD

The theoretical framework of our analysis of the arguments incorporates three elements:
(1) the fundamental principles of bioethics,
(2) the fiduciary model of the physician-patient relationship as a special relationship governed by the above principles and generating particular moral responsibilities for those involved, and
(3) the moral tenet of the inherent dignity, identity, equality and freedom of every human being. Next, we elaborate on each of the three components.

3.1 The fundamental principles of biomedical ethics

In biomedical ethics, the morality of a practice is evaluated by appealing to a set of principles that form the core of biomedical ethics, and on which the various ethical theories converge. These principles are:
1) the principle of autonomy, or self-determination, which generates an obligation to respect patient decision-making;
2) the principle of nonmaleficience (primum non nocere), which leads to the obligation to “do no harm”;
3) the principle of beneficence, giving rise to the physician’s obligation to promote the best interest of the patient; and
4) the principle of justice understood as fairness in the distribution of risks and benefits in health care [5] Ethicists differ on how we should understand the scope and weight of these principles, i.e., how broad the principles are and whether they are absolute or prima facie [10]. There is, however, a wide agreement that these four principles are the relevant action-guides, which regulate the physician-patient relationship and set the rules of ethical conduct in medicine5.

3.2 The fiduciary nature of the physician-patient relationship

The relationship between the physician and the patient is a special, privileged relationship, which is referred to as “fiduciary”. The meaning of this term comes from the Latin fiduciarium, and means “one in whom trust, fiducia, is reposed”. It characterizes the position of trust and confidence, which one person (e.g., the physician) occupies relative to another (e.g., the patient). The special relation-

5 Childress (above). See also [58].
ship between physicians and their patients reflects the structural inequality between them due to the vulnerability of the patient and the specialized knowledge and skills of the physician. The latter who is placed in a relationship of confidence to the patient, who is in a position of vulnerability and dependency to the physician. Examples of fiduciary relationships are those between a parent and a child, an attorney and his client, a guardian and her ward. Morally and legally, fiduciary relationships create more stringent obligations that the ones present between ordinary individuals. The fiduciary is required to protect the interests and well-being of the dependent individual and to act solely in the interest of the person whom he represents” [24] and has the obligation “to safeguard the interests of another person or entity” [25]. The fiduciary nature of the physician-patient relationship generates moral obligations for the physician to act always in the best interest of the patient and the patient alone, to make decisions, which promote the patient’s best interest and well-being, and not to take advantage of the vulnerabilities of the patient [5: pp. 10, 104, 306; 58: pp. 66, 94].

3.3 The inherent dignity, identity, equality and freedom of the human being

The third pillar of biomedical ethics, which informs our ethical analysis of the LOD is the humanist understanding that the human being has inherent worth and dignity, which are independent from and precede social interactions and relationships. This view is expressed succinctly in the 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, which affirms “the need to respect the human being both as an individual and as a member of the human species and recognizing the importance of ensuring the dignity of the human being” [13: Preamble]. Article 1 emphasizes the moral imperative of respect for human beings, “their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine”. Article 2 of the Convention further elaborates on the primacy of the human being: “The interests and welfare of the human being shall prevail over the sole interest of society or science.” This point is of special relevance to LOD, which involves the need to balance considerations about the well-being of the patient in need of an organ and the safety and welfare of living donors with questions about broader societal interests in reducing health care costs, maximizing benefits and allocating optimally such a valuable but scarce resource as transplantable organs.

In the reminder of this Deliverable, we use the above three components as standards for evaluating the morality of LOD and the ethical quality of the arguments for and against LOD with a focus on the implications of these arguments for medical ethics and the physician-patient relationship.

Ethical Analysis of the Moral Permissibility of LODT

1 Morally relevant features of LOD as a medical practice.

To understand why LOD continues to be ethically controversial, one ought to consider the peculiar nature of this activity or, to be precise, the nature of the various activities encompassed in LOD. It includes a set of medical procedures resulting in the removal of an organ or part of an organ from a health living person and transplanting it into another individual, who is sick and needs the transplantation in order to be restored to health. Compared with other types of medical treatment, LOD represents a bold departure from traditional medical practice in at least two ways: Firstly, unlike other medical encounters, LOD involves not only the physician and the patient who is in need of an organ, but also another, healthy individual, the donor, who is not a patient but becomes one in the act of donation. Thus, in LOD, the traditional physician-patient dyad is expanded to a triad that
includes a third major stakeholder, the donor. This expanded relation generates new responsibilities among those involved. These responsibilities are not present in medical practice in general and had not been addressed in previously existing normative frameworks regulating medical practice, i.e., professional ethics, oaths and codes, laws and policies. Therefore, LOD poses a normative challenge to the traditional notion of medical practice and to the professional identity of medicine.

Secondly, LOD is unlike other medical treatments in that it involves subjecting a healthy individual (the donor) to an invasive medical procedure primarily for the benefit of another (the recipient) and without a health benefit for the donor [42: p. 197; 4: p. 617]. The removal of an organ from a healthy donor is a *prima facie* violation of the fundamental ethical proscription against harm [33: p. 3261], which is at the core of morality\(^6\) and the professional ethos of Western medicine\(^7\). The ostensible tension between the good of the recipient and the harm to the donor creates a moral dilemma, which is inherent in LOD but hardly occurs elsewhere in medicine\(^8\). What is more, this dilemma involves the very essence of medicine which, for millennia, has been defined by the moral requirement to do good and avoid harm, expressed in the principles of beneficence and non-maleficence, respectively. It is not surprising, therefore, that LOD continues to raise moral concerns and that it requires moral justification even after years of successfully helping patients with little or no ill effects on the donors.

When put in this perspective, the debate about the moral permissibility of LOD becomes more than just an obstinate academic exercise in hair splitting. It is proxy for a larger polemic on the proper mission and boundaries of medicine in our technologically advanced society on par with discussions about the legitimate boundaries of human experimentation, cosmetic surgery and various forms of human enhancement.

### 2 The moral challenges of LOD

The most fundamental question raised by LOD is whether this practice is morally permissible and whether the inevitable harm and risks to the donor could be morally justified (the harm argument) and under what conditions.

#### 2.1 The major moral dilemma of LOD: the harm to the donor.

Harm is defined as uncompensated loss representing “thwarting, defeating, or setting back some party’s interest” [5: p. 152]. Thus understood, harm is to be distinguished from wrongdoing, or injury, which is a moral term and signified a violation of a person’s rights. In the bioethics literature, there is broad agreement that the fundamental moral dilemma in LOD is the inevitable harm and risk to the healthy donor. This problem was pointedly stated by Carl Elliott in his 1995 article *Do-
ing Harm: “The worrying part [of LOD] is the chance of harm to a health donor” [20: pp. 91-96]. This inevitable aspect of LOD is often noted by proponents and opponents alike. Although in the intervening time LOD has become much safer for both the recipient and the donor with mortality risk for live kidney donors around 0.03% [16] and for live liver donor ranging between 0.2%-0.5% [11, 21], the potential for donor harm remains and is inherent part of the practice of LOD, which sets it apart from other medical procedures: “It is important for those who practice in what is now a standard and routine domain of clinical care not to forget that the first transplant procedures transgressed well established moral boundaries” [27: p. 151]. The moral boundaries, which LOD transgressed are set by the principles of beneficence and non-maleficence, which LOD appears to violate: “For the first time in medical history, volunteer donor was subjected to real and significant harm (surgical removal of a kidney) to provide benefit to another individual. Clearly this activity appears to violate the first rule of medicine *primum non nocere*” [33: p. 3261].

2.2 Moral justifications for LOD

There are several strategies for the proponent of LOD to counter this central concern and to defend the morality of LOD. Firstly, it could be argued that LOD does not constitute harm to the donor provided certain conditions of LOD are met, e.g. if the donor consents to the harm [14: pp. 95-109]. Secondly, one could argue that LOD causes certain, albeit small harm to the donor but that this harm can be justified by the benefits of LOD to the recipient. Thirdly, one could argue that the harm to the donor could be justified and offset by the benefits, which LOD holds for the donor. Here, we consider these various justifications and argue that only the third one represents a plausible defence of LOD.

LOD, injury and valid consent

Some proponents of LOD try to block the harm objection by pointing out that an act is not morally wrong if it does not lead to an injury [14]. Since harm is not the same as an injury, and since injury does not occur if one consents to the harmful act, the donor’s consent to LOD precludes injury and justifies the act. This reply is grounded in the principles of autonomy and respect for the self-determination of autonomous living donors. It is also consistent with the individual’s freedom to determine what happens to his body even if this involves taking risks and self-harms. Autonomy is a central value both in social and political philosophy and in biomedical ethics and as such, it seems to provide solid justification for LOD. Therefore, the autonomous donor’s consent becomes a mandatory requirement for LOD. However, a number of authors question whether donors are capable of choosing autonomously and giving the informed consent required to justify LOD. Some argue that genuine informed consent for LOD is impossible because the donor is often emotionally related to the recipient (in the case of direct donation, e.g., a mother to her child, or a LOD between spouses). On this view, such closely related donors are compelled to donate on emotional and psychological grounds or because they feel pressured to do so [8; see also 50: p. 507], which violates the requirement for voluntariness as a component of informed consent. Others worry that even if the donor is not compelled by emotional ties, informed consent for LOD is still precluded due to the uncertainties about the outcome and possible complications of the donation. On this view, consent for LOD is never fully informed and thus, it is not fully valid, and is in fact a myth [23: pp. 1245-1251]. In response to the charges that informed consent cannot be achieved unless the donor is impartial and fully informed, Spital and Taylor cite the Nuffield Council’s observation that what matters in informed consent “is not that consent is complete, but that it be genuine” [54: pp. 203-204]. This requirement of authenticity is clearly met in the case of emotionally related donors.
suggesting that their decisions to donate are as valid as those among impartial unrelated individuals. Furthermore, the requirement for full information is an ideal and it is hardly ever met in practice not only in the context of organ transplantation but in most areas of medical treatment. Therefore, there is no reason to make full information a requirement for valid consent in LOD provided it is not required or achieved in the case of other medical interventions.

**LOD and the moral limits of appeals to autonomy**

Thus, appeals to autonomy seem to offer a promising justification of LOD despite the inherent harm to the donor because ethicists recognize the right of competent adults “to act altruistically, even if it entails some small but serious risk” [48: pp. 151-172]. However, autonomy may be a necessary condition for morally justified LOD but it is in no way sufficient. This becomes evident when physcials are faced with repeat living donors or donors who wish to donate vital organs thus endangering their lives. Renee Fox from Stanford University and William De Vries from Utah have reported cases of health volunteers offering to become living heart donors or to have an artificial heart implanted solely for research purposes [20: p. 92]. Although rare, such cases do exist and they are treated as morally problematic for at least two reasons. Some argue that individuals are not morally justified to endanger their lives even if this is their autonomous choice. Others argue that even if individuals have such a right, it does not generate an obligation on the part of others to enable the individual who wishes to risk his life. Physicians are moral agents and they need not fulfil any autonomous wish of the patient unless it is medically indicated. This moral boundary is meant to protect the moral and professional autonomy of the physician as a moral agent and to allow him a level of moral responsibility. Thus, Schwartz argues that patient autonomy does not entitle a patient to any treatment the patient may wish to receive and for any reason but only to treatments which are consistent with the scope of medical practice and are deemed appropriate by the physician. This understanding would rule out futile treatments or procedures which have no therapeutic purpose, such as requests for surgical amputations of healthy limbs due to a patient’s distorted body image. Consequently, LOD policies and laws commonly contain prohibitions against donation, which would result in ending the donor’s life [34: p. 9]. What is less clear, however, is how to draw the line between morally acceptable and morally unacceptable risk to the donor without running the risk of unjustified paternalism. The response is suggested by the moral theory of moral philosopher Immanuel Kant. When it comes to LOD, Kant is often misunderstood and portrayed as a moral absolutist who would reject LOD altogether. As an illustration, authors often cite Kant’s obsolete proverbial tooth example, which is then easily dismissed as silly and unscientific [42: p. 207; see also 18: p. 50]. It occurs in *The Metaphysics of Morals* where Kant states: “To deprive oneself of an integral part or organ (to maim oneself) – for example, to give away or sell a tooth to be transplanted into another’s mouth (...) and so forth – are ways of partially murdering oneself” [31: p. 547]. The tooth example is indeed a silly, unfortunate illustration from Kant’s otherwise complex theoretical view on self-mutilation and its relation to the moral self. What is often overlooked is that the tooth example appears in the context of Kant’s discussion of the distinction between the juridical and the moral self, and their relation to personhood and agency. On closer examination, Kant’s moral philosophy proves compatible with most types of LOD. What Kant would object to is not LOD as such but only these types of LOD which could render the donor incapable of moral agency (which is consistent with his strong belief in autonomy). Thus, Kant’s outlook on ethics would be compatible with certain types of living donation while also providing grounds for drawing the line to problematic practices such as repeated LOD and LOD which threatens the donor’s moral agency either by self-destruction (i.e., death) or by moral degradation (i.e., selling oneself) [7: pp. 129-39].

The second limitation on autonomy as a justification for LOD comes from the moral agency of the physician as a person and professional. While the donor may be in his right to choose to donate
an organ, and while we may understand and justify the willingness of the recipient to accept the gift as a last resort, there is no ostensible justification for the physician's decision to remove the organ from the body of the healthy donor. This problem is pointedly expressed by Ellicott: “If a patient undergoes a harmful procedure, the moral responsibility for the action does not belong to the patient alone; it is shared by the doctor who performs it. Thus a doctor is in the position of deciding not simply whether a subject’s choice is reasonable or morally justifiable, but whether he (the surgeon) is morally justified in helping the subject accomplish it” [20: p. 95]. In fact, prior to the donation, the physician stands in no relation to that donor whatsoever so even referring to the potential donor as a patient is already a misleading and morally loaded way of describing the problem. This issue moves the debate from the ethics of LOD to the ethics of transplantation from living donors which expands the circle of stakeholders beyond the traditional physician-patient relationship. Is there a justification for removing organs from healthy donors? The common response is to justify the removal of organs by appealing to the benefits of the donation. But the removal of an organ has no therapeutic value for the donor, and indeed may lead to complications, pain, discomfort and, occasionally, may result in death. This raises the question: what exactly is the benefit and for whom?

**LOD and benefits**

There are two possible accounts of the benefit of LOD. Most authors point to the substantial benefits which the recipient derives from LOD in terms of improved health and quality of life. This, Kulkarny et al. explain: “The justification for exposing the living donor to real and significant risks was balanced by the fact that the recipient who suffered end-stage kidney failure had no acceptable treatment options available” [33: p. 3261]. Such responses presuppose that the risk to the donor is weighed against the benefit of the recipient [see also 46: pp. 1148-1153]. This line of reasoning is as common in the literature as it is flawed. It engages in two errors: first, it attempts to draw an interpersonal comparison between the interests of two distinct and separate individuals, which is implausible and places the comparing physician in the idealized “god’s eye” perspective of someone who has privileged access to the circumstances of the affected individuals and has also the moral authority to judge their best interests objectively. Secondly, the doctor is placed in the conflicting role of judging both the donor and the patient, which goes against the fiduciary role of the physician who ought to advocate solely for the benefit of her patient alone. Hence, the requirement that donors and recipients are evaluated by separate physicians. For a physician to fulfil her responsibility to the donor and avoid a conflict of interest, the physician must compare the benefits to the donor with the risks for that same donor. This is exactly what proponents of LOD maintain when they try to demonstrate the benefits of LOD for the donor himself. As noted by Spital, establishing the benefit to the donor “is the key to justified living organ donation” [55: pp. 105-109]. Indeed, donor benefit is what addressed the key concern about the inherent harm of LOD to the donor. The benefit justifies the donation by providing compensation to the affected party (the donor) for the risks and harm involved in the donation.

**The moral quality of LOD between individuals who are emotionally and/or genetically related**

The list of donor benefits ranges from psychological benefits such as a sense of satisfaction and self-fulfilment to more tangible benefits when the donor has a close relationship to the recipient, e.g., helping one’s loved one regain one’s health, benefitting from having the loved one in one’s life, being relieved from the burden of providing care for the recipient etc. If we agree that benefit to the donor is indeed the key to justifying LOD, it is easy to understand why there is wider acceptance
of LOD among individuals who are emotionally related yet donors who are willing to donate to strangers are greeted with suspicion reflected in the fact that very few countries allow LOD among complete strangers (“altruistic donation”).

The moral quality of LOD between individuals who are not emotionally and/or genetically related

Giving an organ to an anonymous recipient seems irrational as the benefit to the donor is difficult to discern, especially given the risks involved. However, objections to unspecified (altruistic) donation are not based on the mere presence of risk to the donor but on the presumed absence of benefit to him, which benefit is the morally redeeming outcome of the risky behaviour (the donation). Consequently, donors who lack a close relation with the recipients appear morally and rationally suspect: they either expose themselves to a risk without corresponding benefit, which is irrational and/or reckless, or else they are presumed to have a hidden benefit such as an ulterior motive, i.e., monetary gain. It is for this reason that unspecified donation is often viewed as a first step to organ trade, and is thus condemned [35: pp. 17-20; see also 26: pp. 67-69].

LOD, fairness, benefit and compensation

Ultimately, what gives rise to the moral requirement for benefit to the donor is the principle of justice and the underlying strong intuition that it is required, as a matter of fairness, that benefits and burdens in life are equitably distributed among persons, and that those who bear the greatest burden are precisely those who stand to benefit the most from a given action. The principle of justice is widely shared both as a principle of social and political life and as a principle of morality. In medicine, it affects views and policies on allocation of scarce resources, participation in clinical studies and indeed, organ donation. And while the principle itself is fairly non-controversial, the difficulty begins when we attempt to determine what counts as benefit in specific circumstances and how much of a benefit is justified given the burdens attached. When it comes to medical treatment, the determination of acceptable balance of burdens vs. benefits is left to the patient on grounds of respect for autonomy, and because the patient is the one who has the greatest stake in the decision. Individuals vary greatly in how much discomfort, pain or suffering they are willing to tolerate and to what ends. This is a matter of value judgment, and as John Stewart Mill aptly notes, on matters of value, the affected individual is best suited to be the judge [39]. Yet, when LOD is concerned, ethicists usually refuse to grant donors the right to determine consistently and for themselves what level of benefit, if any is acceptable to offset the risk and harm of a donation. This is equally true when it comes to acceptable harm to the self and when it comes to acceptable benefit in terms of the good of another. In fact, ethicists, legislators and policy makers are particularly reluctant to allow individuals to determine what constitutes acceptable donor benefits when it comes to unspecified donation (to strangers). However, if the underlying moral concern is that burden must be fairly compensated, then there is no reason to deny to donors whatever benefit they choose for themselves and including monetary gain because if the primary concern is fair distribution of burdens and benefits, money is indeed a socially accepted way of compensating others, especially strangers for their contributions to the well-being of others. Thus, the justice requirement, when applied consistently to LOD opens up the possibility for justifying payments of living donors as a compensation for unspecified anonymous donation. Indeed, a number of moral philosophers have called for introducing a regulated market of organs as a way of improving organ donation [37: pp. 2007-2017] and some even consider it morally obligatory [57].
LOD and markets for organs

When applied to LOD, the principle of justice seems to weigh in favour of selling organs. However, even if this is the logical conclusion of the argument, we are not obliged to follow it if it generates implications which are themselves morally repugnant. To determine this, we need to ask ourselves, Do we want organ selling? Are we prepared to go that far? Most will answer in the negative for the numerous reasons outlined by those who have explored in depth organ markets as an alternative, and refuted it [52: pp. 1349-1350]. They argue that markets for organs do not work, they alienated potential donors, dehumanize them, exploit them and diminish recipients, donors and physicians. We concur with them that the mechanisms of the market are not well suited for addressing the complexity of organ donation. If we need to draw a line in the sand of the moral universe, we may be better served by refusing certain forms of LOD, namely unspecified LOD, rather than allowing a morally repugnant practice to undermine human dignity and worth. Furthermore, before we condone a morally problematic practice such as organ sales we may do better to look for alternatives elsewhere, in the promise of new technologies such as stem cells therapies and cloning of organs from the tissue of the recipient, which would allow transplantation to proceed free from moral controversies and medical complications demonstrating yet again that good ethics makes for good science.

Conclusion and Recommendations

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. Yet, none of them provides unqualified justification for LOD without regard of the moral responsibilities of the physician or the moral status of the donor. On the contrary, 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. As such, LOD requires strict safeguards to establish valid consent, benefit to the donor and conflict-free assessment by a fiduciary physician. Vulnerable populations do not meet these requirements and therefore LOD from minors and mentally handicapped individuals is not morally permissible. Some donor benefit must be present to offset the harms and risk to the donor. 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 the number of reasons stated in the literature against organ sales. Likewise, 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). 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.

Authors contributions

AP developed the research methodology, performed the research, analysed the findings and wrote the Deliverable; YK developed the search strategy, performed the research and approved the manuscript, AI performed the research and approved the manuscript.
Acknowledgments

The authors wish to thank Thomas Gutmann, Bijan Fateh-Moghadam and Leonie Lopp (all from WWUM) and Mihaela Frunza (SACRI) for their collaboration in developing the classification (map) of normative arguments. The authors are grateful to Frederike Ambagtsheer (EMC), Fabienne Dobbelts (KU Leuven) and Annette Lennerling (UGOT) for their input on the search strategy for the literature review, which served as a background for the map of arguments.

Bibliography


[34] Lopp L. Analysing the normative arguments that dominate the policy arena about necessity and legitimacy of legal restrictions in liver donor transplantation. EU LOD Work Package 3: Legal Restrictions and Safeguards for Living Donation in Europe, Part I: Unrelated Organ Donation.


Appendix 1: Search Strategy for Literature Review

After extensive research and analysis, the search strategies of EULOD-WP2 were adapted to the bibliographical conventions and the underlying organizing key terms adopted by the respective databases.

Search of ETHXWeb and Islamic Ethics Databases
(Kennedy Institute of Bioethics at the Georgetown University)

The Bioethics Research Library (BRL) databases of the Kennedy Institute of Bioethics at the Georgetown University currently hold 310,000 bioethics citations. These include books, book chapters, journal articles and laws. This is one of the largest repository of bioethical information and is publicly available and freely accessible. The Islamic Ethics database is a smaller subset of citations, also accessible within ETHXweb.

The research strategy is adapted to the specific hierarchy and selection of terms and of key terms at BRL. For instance, every single item is already screened to be of “bioethics” nature, so filtering out of medicine-specific topics, such as immunosuppressant drugs is not necessary.

The research strategy calls for grouping the research by legal, theoretical bioethics and applied bioethics. The analysis demonstrated that these categories approximately relate to existing subject categories at BRL as demonstrated in the following table:

<table>
<thead>
<tr>
<th>Search Strategy Terms</th>
<th>Corresponding BRL Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approach</strong></td>
<td></td>
</tr>
<tr>
<td>Legal</td>
<td>Legal</td>
</tr>
<tr>
<td>Bioethics Theory</td>
<td>Philosophical, Analytical, Case Studies</td>
</tr>
<tr>
<td>Bioethics Applied</td>
<td>Religious, Empirical</td>
</tr>
<tr>
<td><strong>Source</strong></td>
<td></td>
</tr>
<tr>
<td>Research</td>
<td>Journals</td>
</tr>
<tr>
<td>Gray</td>
<td>Books, Manuals</td>
</tr>
<tr>
<td>Review</td>
<td>Review</td>
</tr>
</tbody>
</table>

The juxtaposition of Approach and Source yielded eighteen distinct groups of search results, achievable by executing the Boolean searches below. In order to replicate the results, the researcher needs to copy and paste strategies into search box for Boolean Search:

http://bioethics.georgetown.edu/databases/ethxweb/ethxbool/index.html

Additionally, the required data range (1/1/1990-present) should be applied as criteria in each individual strategy. The language selection requirement was to limit the research to the official languages of EU (and Russian). The language selection should be applied as criteria in each individual strategy. All languages in the dropdown list need to be selected, except Japanese, Other (Chinese, Hebrew, and Afrikaans citations) and Serbian. In order to format the results to desired specifications, put ‘Display per Page’ at MAX (bottom of the search page).
Living Donation

1. Living Donation/Legal/Journal Articles
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and le[sc] and ja[pt]})
   \text{Retrievals 20110311 = 28}

2. Living Donation/Legal/Books or Reports
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and le[sc] and (m[pt] or b[pt])})
   \text{Retrievals 20110311 = 8}

3. Living Donation/Legal/Reviews
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and le[sc] and rv[sc]})
   \text{Retrievals 20110311 = 2}

4. Living Donation/Philosophical, Analytical, Case Studies/Journal Articles
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and (ph[sc] or an[sc] or cs[sc]) and ja[pt]})
   \text{Retrievals 20110311 = 17}

5. Living Donation/Philosophical, Analytical, Case Studies/Books or Reports
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and (ph[sc] or an[sc] or cs[sc]) and (b[pt] or m[pt])})
   \text{Retrievals 20110311 = 2}

6. Living Donation/Philosophical, Analytical, Case Studies/Reviews
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and (ph[sc] or an[sc] or cs[sc]) and rv[sc]})
   \text{Retrievals 20110311 = 1}

7. Living Donation/Religious or Empirical/Journal Articles
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and (re[sc] or em[sc]) and ja[pt]})
   \text{Retrievals 20110311 = 67}

8. Living Donation/Religious or Empirical/Books or Reports
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and (re[sc] or em[sc]) and (b[pt] or m[pt])})
   \text{Retrievals 20110311 = 1}

9. Living Donation/Religious or Empirical/Reviews
   \(((19.+[pc] \text{ and } \text{“living donor” or “living donation” or “living organ donor” or “living organ donation”}) \text{ not po[sc]}) \text{ and (re[sc] or em[sc]) and rv[sc]})
   \text{No retrievals for this search 20110106; Still no results 20110311.
Organ Transplantation (General, Excluding Living Donation)

10. Organ Transplantation/Legal/Journal Articles
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and le[sc] and ja[pt]
   Retrievals 20110311 = 412

11. Organ Transplantation/Legal/Books and Reports
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and le[sc] and (b[pt] or m[pt])
   Retrievals 20110311 = 65

12. Organ Transplantation/Legal/Reviews
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and le[sc] and rv[sc]
   Retrievals 20110311 = 11

13. Organ Transplantation/Philosophical, Analytical, Case Studies/Journal Articles
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and (ph[sc] or an[sc] or cs[sc]) and ja[pt]
   Retrievals 20110311 = 192

14. Organ Transplantation/Philosophical, Analytical, Case Studies/Books or Reports
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and (ph[sc] or an[sc] or cs[sc]) and (b[pt] or m[pt])
   Retrievals 20110311 = 25

15. Organ Transplantation/Philosophical, Analytical, Case Studies/Reviews
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and (ph[sc] or an[sc] or cs[sc]) and rv[sc]
   Retrievals 20110311 = 5

16. Organ Transplantation/Religious or Empirical/Journal Article
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and (re[sc] or em[sc]) and ja[pt]
   Retrievals 20110311 = 386

17. Organ Transplantation/Religious or Empirical/Books or Reports
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and (re[sc] or em[sc]) and (b[pt] or m[pt])
   Retrievals 20110311 = 18

18. Organ Transplantation/Religious or Empirical/Reviews
   ((19.+pc not ("living donor" or "living donation" or "living organ donor" or "living organ
donation" or po[sc]))) and (re[sc] or em[sc]) and rv[sc]
   Retrievals 20110311 = 3

Key to Tags used in the Boolean Search:

pc = Primary Classification (focus of the article)
sc = Subject Caption (General Approach – Empirical, Analytical, etc)
Search of PubMed
(the database of the US National Library of Medicine)

PubMed contains vast resources of biomedical literature, including 253,000 citations in bioethics. The search strategy is adopted to adhere to the taxonomy and key terms of the PubMed databases. For instance, the PubMed database references all journals. Hence, the search for journal and review articles will be conducted in PubMed http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed.

Living Donation

1. Living Donation/Legal & Jurisprudence/Journal Articles
   Retrievals 20110322 = 265

2. Living Donation/ Legal & Jurisprudence /Reviews
   Retrievals 20110322 = 56

3. Living Donation/Ethics/Journal Articles
   Retrievals 20110322 = 56
Organ Transplantation (General, Excluding Living Donation)

7. Organ Transplantation/Legal/Journal Articles


Retrievals 20110322 = 332

8. Organ Transplantation/Legal/Reviews

OR German$lang OR Italian$lang OR Spanish$lang OR Bulgarian$lang OR Czech$lang OR Danish$lang OR Dutch$lang OR Estonian$lang OR Finnish$lang OR Greek, Modern$lang OR Hungarian$lang OR Latvian$lang OR Lithuanian$lang OR Polish$lang OR Portuguese$lang OR Romanian$lang OR Slovak$lang OR Slovenian$lang OR Swedish$lang OR Russian$lang)) AND bioethics[sb] AND ("1990"[PDAT] : "3000"[PDAT])
Retrievals 20110322 = 47

9. Organ Transplantation/Ethics/Journal Articles
Retrievals 20110322 = 672

10. Organ Transplantation/Ethics/Reviews
Retrievals 20110322 = 92

11. Organ Transplantation/Empirical/Journal Articles
("organ transplantation"[MeSH Terms] AND bioethics[sb]) AND ("data collection"[MeSH Major Topic] OR “empirical research”[MeSH Major Topic] OR empirical approach[ot]) AND (English$lang OR French$lang OR German$lang OR Italian$lang OR Spanish$lang OR Bulgarian$lang OR Czech$lang OR Danish$lang OR Dutch$lang OR Estonian$lang OR Finnish$lang OR Greek, Modern$lang OR Hungarian$lang OR Latvian$lang OR Lithuanian$lang OR Polish$lang OR Portuguese$lang OR Romanian$lang OR Slovak$lang OR Slovenian$lang OR Swedish$lang OR Russian$lang]) NOT review[pt]) AND (“1990”[PDAT] : “3000”[PDAT])
Retrievals 20110322 = 257

12. Organ Transplantation/Empirical/Reviews
Retrievals 20110322 = 11

All books, reports and reference literature is in NLM catalog. Therefore the searches for “gray” literature will be conducted in the NLM catalog http://www.ncbi.nlm.nih.gov/sites/entrez?db=nlmcatalog.
Ethical Analysis of the Arguments for and against Living Organ Donation Title

13. Living Donation/Legal & Jurisprudence/Books

Retrievals 20110322 = 9

14. Living Donation/Ethics/Books

Retrievals 20110322 = 21

15. Living Donation/Empirical/Books

Retrievals 20110322 = 4

16. Organ Transplantation/Legal/Books

Retrievals 20110322 = 11

17. Organ Transplantation/Ethics/Books

Retrievals 20110322 = 199

18. Organ Transplantation/Empirical/Books
Retrievals 20110322 = 101
Analysing the Core Normative Arguments that Dominate the Policy Arena about Necessity and Legitimacy of Legal Restrictions in Living Donor Transplantation

Leonie Lopp

University of Muenster

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I Introduction

There are not enough donor organs available to help all patients suffering from organ failure. Especially concerning LOD, there are, however, also legal reasons for this shortage. LOD regimes create, in part, an artificial scarcity. Several different types of LOD are medically possibly, but prohibited by law. As the German Constitutional Court declared in its 1999 ruling on LOD, “Whenever legal regulations entail that a citizen in need of treatment is denied a therapy which, according to the state of medical research, could be provided to him or her, and which would entail a prolonging of life or at least a substantial mitigation of the ailment, the constitutionally guaranteed basic negative right to life and health is infringed upon.” The Charter of Fundamental Rights of the European Union also protects the right to life and the person’s right to integrity. It does not mention LOD in particular, but the inclusion of these two rights in the Charter is nonetheless important for LOD. These two rights should therefore not be ignored in LOD.

Living donor kidney transplantation has become an established medical procedure worldwide, but can still be considered as an underutilized resource in many countries. It is therefore crucial to establish an appropriate legal framework for LOD (to guarantee the voluntariness of donors), separate from unjustified legal barriers and misguided rationales. This article systematically presents the arguments for the necessity and the legitimacy of legal restrictions on LOD, and subjects them to closer scrutiny.

Fifteen years ago, it was said that Europe suffered from a disease called HIL (“Highly Inappropriate Legislation”) in the field of LOD. This may no longer be completely true. Finding the best regulatory model for LOD, however, requires a critical examination of the principles underlying different policy options and legal models.

II Terminology

A rough distinction is made between specified LOD and unspecified LOD. The term specified LOD comprehends all LODs with the intent to help a specific recipient. This includes direct LOD, but indirect LOD as well. Direct LOD means that a person donates directly to the intended recipient, for example, when a parent donates to his child or a child donates to his parent. Indirect LOD means that a person donates to help a specific recipient, but the donation is only indirect. The organ from the related donor is not directly transplanted into the recipient. The donation still allows the recipient to receive an organ, because he receives an organ from a stranger in return for the donation of
the relative which is given to another person as well. This type of LOD includes cross-over LOD, unbalanced living paired exchange, living paired cascade exchange, pool donation and list-paired exchange. The opposite of specified LOD is unspecified LOD. In such a case, a person donates an organ to an anonymous recipient. This is LOD to a stranger. Directed altruistic LOD can either be classified as indirect LOD or as unspecified LOD. Another type of LOD, namely, unspecified non-directed donation catalysing cascade exchanges, connects indirect LOD and unspecified LOD. As seen, several types of LOD exist.10

III Arguments serving to restrict living organ donation

1) To start, we analyse whether LOD violates the rule to do no harm.
2) We address whether LOD can be voluntary.
3) We consider the potential social pressure.
4) We address the problem of organ trade.
5) We consider the potential social pressure.
6) We address the problem of organ trade.
7) We examine aspects concerning justice and equality.
8) We examine special groups of donors individually.
9) Arguments against specific methods and programmes to increase LOD are presented.
10) After describing the relevant material aspects, we address procedural issues.

There is no single or unified moral theory to date. Moral reasoning and approaches to medical ethics are as pluralistic as our societies. Ethical theories are composed of varied, partly incompatible, sets of premises and intuitions, each containing diverse strengths and weaknesses. To create a common ground for intertheoretical moral discussion and a practical approach for ethical (and policy) decision-making, mainstream medical ethics often rely on principles to inform its reasoning process. The most relevant of these principles are

(a) respect for persons, including their autonomous choices and actions;
(b) beneficence, including both the obligation to benefit others (positive beneficence) and to maximise good consequences – i.e., to do the greatest good for the greatest number (utility);
(c) justice, the principle of fair and equitable distribution of benefits and burdens and finally
(d) nonmaleficence (non nocere), the obligation not to inflict harm. In conflicting cases, these principles have to be applied to specific circumstances and balanced against each other.11

Although principalism is severely criticized in moral and legal theory, it serves as a means to structure the debates for the purposes of this article.

1 The Harm-Argument

LOD involves surgery on a donor. Every surgery is comprised of certain risks, even the risk to die. This applies to LOD as well, although the mortality rate is very low. Therefore, LOD is sometimes considered a violation of the principle of nonmaleficence,12 or the rule not to do harm to anyone

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9 With respect to the used terminology see Dor et al., 2011 Transplantation 1 ff.
10 The different types of LOD that have just been named will be explained further below.
else *(primum non nocere).* Many disagree that LOD is a violation of this principle, citing the principle of *volenti non fit iniuria* for support. They argue that the donor herself voluntarily decides to take part in the surgery, thus exercising her right of autonomy and therefore cannot be considered harmed. Hence, an ethical conflict between respecting autonomy and the rule to do no physical harm to healthy persons exists.

1.1 Autonomy

First, we focus on the concept of autonomy and examine its historical background. Second, we regard the concept of informed consent and how it specifically relates to LOD.

1.1.1 Concept and historical background of autonomy

According to Kant, *moral* autonomy refers to the capacity to impose the (objective) moral law on oneself, while *personal* autonomy refers to a trait that individuals can exhibit relative to any aspects of their lives; it is not limited to questions of moral obligation. The term autonomy describes a right to self-determination; this includes the right to exercise control over one’s own body. This even applies to self-harming behavior. Given the weight of the concept of autonomy, one could argue that the donor’s autonomous decision is not only necessary, but also a sufficient condition to justify LOD, including unspecified LOD.

In contrast, there have always been ethical positions claiming that personal autonomy cannot justify LOD. In the past, Christian theologians held that we ourselves are not the rightful owners of our bodies, rather God is. Traditionally, many believed that a person was not allowed to deprive himself of an organ for the benefit of another person. Such an act was considered to be self-mutilation. Catholic moral theology brought forward a totality theory with regard to LOD, stating, “Anybody severability is an impermissible interference with nature and God’s order, affecting the physical completeness of a human being. [...] Only a non-healthy body part may be removed for the benefit of the organism as a whole.” From a traditional theological standpoint, LOD should be completely prohibited. Kant transformed this Christian notion into a philosophical one. He obviously did not directly address LOD, but he did discuss tooth transplantation in 1797. He stated, “To

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14 This principle says that, in case the person concerned consents, no injury is done [Benke/Meissel/Luggauer (1997), p. 406; Daar et al., Vol. 11 Transplantation Review 95, 101 (1997); Lieberwirth (2007), p. 302].
17 Christman (2011); Dworkin (1988).
deprive oneself of an integral part or organ (to maim oneself) – for example, to give away or sell a tooth to be transplanted into another’s mouth (…) and so forth – are ways of partially murdering oneself.” Applying this statement to LOD leads one to assume that Kant would have criticised the procedure as immoral.

Firstly, a deeper examination of Kant’s concept of autonomy reveals that it could be compatible with most types of LOD. On the other hand, the examination reveals that it could also be used to support strong moral and also legal-philosophical arguments against allowing behaviour (including LOD) that may render the donor incapable of moral agency. Secondly, Kant explicitly states that the (theoretically contested) conception of ‘duties to oneself’ that he draws upon in his example is confined to morality and not applicable in policy making and the law. Christian (especially Catholic) doctrine has given up its totality theory as far as LOD is concerned. Organ donation in general is now seen as an act of love within Christianity.

Thus, autonomy used to be insufficient from a Christian and philosophical point of view to justify LOD, but this can now be considered as obsolete.

1.1.2 Informed consent

The principle of autonomy is very general. The concept of “informed consent” is more specific to medical interventions. The purpose of informed consent is to ensure that the patient’s autonomy is respected. Consent procedures are there to limit deception and coercion. Informed consent for LOD is a standard requirement in the countries considered. But, not every country agrees that informed consent is sufficient to justify LOD. These countries use either paternalistic or public interest rationales to argue that informed consent is insufficient for LOD. In England, France, Italy and Spain, the patient’s consent is required to justify LOD, but is not held to be a sufficient condition. Rather, they require an additional legitimising element. In Austria, Germany, the Netherlands, Portugal and Switzerland, consent is principally considered adequate to justify LOD. Competent adults are seen as having the right to expose themselves to risks and are also seen as being capable of accepting any negative consequences that may accompany their risks, so long as their behaviour does not harm any third person or the general public. An autonomous person makes his own judgment concerning his bodily integrity.

Nevertheless, even in these countries, the scope of the patient’s autonomy is still limited. The most important, generally shared limitation is that LOD is illegal if it would end the donor’s life or would be directly life-threatening. In addition, several countries declare consent that goes against ‘good morals’ void.
Thus, LOD is not at variance with the principle of autonomy. Since this principle is in an ethical conflict with the principle of nonmaleficence, we examine whether LOD contravenes the principle of nonmaleficence in the following.

1.2 Living organ donation contravenes the principle of nonmaleficence

The principle of nonmaleficence, prominent in the Hippocratic tradition of medical ethics, asserts an obligation not to inflict harm. A person is harmed if his interests are adversely affected. According to this definition, it is irrelevant whether one's rights are violated, or an injustice is inflicted upon the person concerned. The principle of nonmaleficence is thus significant when surgery is performed on a healthy person, as in the case of LOD.

LOD is unique insofar as it involves two patients, and, in most cases, does not have any benefit for the physical health of the donor. Although, especially with regard to living kidney donation, the risks are fairly modest, they are in no case negligible. Therefore, a contravention of the principle of nonmaleficence may be assumed.

However, even according to the principle of nonmaleficence, it is morally acceptable for a person to become a living organ donor if the benefits are expected to outweigh the expected physical (and possibly also psychological) risks to him. All things considered, the overall well-being of a person may be improved by becoming a living organ donor. Well-being is more than physical health. Psychological and emotional advantages and an increase of self-esteem may counterbalance the donor’s pain, discomfort, anxiety and risk. This is also true in the case of unspecified LOD. When evaluating the harm to the organ donor, harm must not be interpreted too narrowly. Moreover, potential donors might also suffer “psychosocial and moral harms if they are prevented from serving as a donor.” Finally, if harm means adversely affecting one’s interests, then the donor’s critical interests in restoring someone else’s health, and in being the person who acts in this way, must also be taken into account.

On the other hand, when using complex notions of benefits and harms to assess the interests of persons in a vulnerable position, those who are heavily dependent on the donor (e.g., underage children) may try to discourage the donor from donating; it might even serve as a moral contraindication in special cases.

Nevertheless, the principle of nonmaleficence is not necessarily against LOD. In the following, (1) we describe the consequences for LOD that are drawn from the application of the principle of nonmaleficence. (2) Afterwards, we present the position of the surgeon and the transplant team in the process of LOD.

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36 The Hippocratic Oath states, inter alia: “I will apply dietetic measures for the benefit of the sick according to my ability and judgement; I will keep them from harm and injustice.” See e.g. Edelstein (1943).
41 Daar et al., Vol. 11 Transplantation Review 95, 102 (1997).
(3) An acceptable risk-benefit ratio in LOD is examined.
(4) The role of common welfare in LOD is explained.
(5) We ask if a special relationship is necessary for LOD.
(6) The principle of subsidiarity is considered briefly.

1.2.1 Consequences of the principle of nonmaleficence

As a consequence of the application of the principle of nonmaleficence, some argue against LOD in general, while others only conclude that LOD has to be restricted to direct LOD.

Those interested in putting an end to LOD in general pursue an absolutist approach and do not see any reason to allow this violation in particular cases.\(^{46}\)

This approach completely fails to take into account the respect for autonomous choices and the principle of beneficence.\(^{47}\) Concerning the latter, the overall benefit of the donor and the recipient in the harm-benefit equation is increased in LOD.

In contrast, many suggest restricting LOD to direct LOD. They claim that a restriction would minimise the risks to the donor's health.\(^{48}\)

Opponents rightfully point out that the donor's risks are equally high in direct, indirect and unspecified LOD.\(^{49}\) Consequently, a stringent application of the rule not to cause (physical) harm would prohibit all LODs, including those within families.\(^{50}\)

1.2.2 A reminder on the difference between Liberties and Duties

LOD directly concerns the organ recipient and the donor, but also the transplant team.\(^{51}\) The transplant centre and the surgeon have to decide whether the surgery will be performed or not.\(^{52}\) However, refusing merely because the physician disagrees with the values of the patient's life plan may be a profound affront to dignity and independence.\(^{53}\) But the transplant team, as a moral actor, is perfectly entitled to take into account its responsibilities for all patients and the transplant system as a whole. Hence, removing legal barriers to LOD does not oblige physicians to actually perform everything they are allowed to perform.

How do these facts distinguish between direct LOD and other types of LOD? Since unspecified LOD is still rather seldom, surgeons and transplant centres might fear that the social support is rather dissatisfying for unspecified LOD.\(^{54}\) However, one should bear in mind that surgeons – from a medical and professional perspective – proceed in the same way, regardless of the type of LOD.\(^{55}\)

Also, the potential harms and risks are the same for direct LOD and for unspecified LOD. Hence, the transplant team should decide for each case individually – for direct LOD as well as for indirect and unspecified LOD.

1.2.3 Limits to the acceptable risk-benefit ratio

For those who regard the principle of nonmaleficence as relative instead of absolute, the benefits to the donor and recipient resulting from the LOD must outweigh the risks accompanied by it. Such a risk-benefit ratio cannot be determined by medical (or psychological) facts alone without taking into account the donor’s (and the recipient’s) personal value judgements. This causes the legal limits placed on LOD to vary, apart from the fact that LOD cannot be justified if it kills the donor.

1.2.4 Common welfare

Common welfare means the interests of everyone (in a country) are considered, instead of only one person or a few. The German Federal Constitutional Court uses common welfare as one justification for the restrictive orientation of the German Transplantation Act. This approach can be classified as hard paternalism, which is in conflict with the donor’s right of self-determination – a right guaranteed by constitutional law in many countries.

1.2.5 Special relationship is required for living organ donation

Many believe that a special relationship is required for LOD. They either state that (1) unrelated donors do not benefit as much from LOD as related ones or that (2) only the special relationship between donor and recipient justifies LOD.

(1) Many argue that unspecified donors do not benefit as much from LOD as direct donors. Donors in an unspecified LOD do not have the opportunity to witness the benefits that arise from the act of donation for the organ recipient. This belief prohibits unspecified donors from donating; they are not permitted to take the same risks as family members. The possible consequences that could result from a prohibition of LOD are also considered. A prohibition to donate prevents any potential donor from exercising her right to choose. With respect to direct

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60 Cf. German Federal Constitutional Court, January 22, 2011, Case No. 1 BvR 699/06, at 47.
61 Gutmann, in Middel et al. (ed.) (2010), p. 28.
Analysing the Core Normative Argument

LOD, in addition, relatives often feel a very strong motivation to help each other in times of need; this typically does not apply in the same way to unspecified LOD.65

(2) Some believe that a special relationship between donor and recipient is necessary because it leads to a positive obligation between them.66 Proponents of this radical thesis claim that the justification of LOD lies exclusively in the special donor-recipient relationship because each LOD involves a surgery that puts a healthy person at risk.67 Second, they claim that the love between donor and recipient might lead to the wish to help a suffering relative.68 Third, they argue that the suffering of another person is felt more intensively if the person concerned is a relative or a close friend,69 and that the donor’s motivation is generally influenced by the quality of the donor-recipient relationship.70

Both approaches give reasons to assume that prohibiting direct LOD creates a heavier burden for both donors and recipients, intensely infringes on their right to autonomy and, in the case of the potential recipient, infringes on the legally protected interest to life and health.71

None of these arguments is convincing enough to prohibit unspecified LOD, though. One cannot conclude that the special responsibilities only apparent in direct LOD are the only normative foundation of LOD; this is a non sequitur argument.72 If one differentiates direct LOD from other types of LOD, he fails to grasp what it means to be respected as a person capable of making moral choices, and disregards the fact that the moral value of beneficence, of saving lives and restoring health, does not depend on there being a close relationship between the parties involved.73 The only relevant question is whether the donor cares for the needs of another. This applies to every (noncommercial) LOD, regardless of the relatedness of donor and recipient.74 Hence, both types of LOD should be treated equally;75 each LOD should be judged individually.

1.2.6 The Principle of subsidiarity

The aspect of subsidiarity concerns the question of whether LOD constitutes a primary cure option or merely a subordinate one. This issue includes two aspects:

(1) First, we discuss whether the option of transplanting an organ donated by a living person is subordinate to transplanting an organ donated by a deceased; this issue is especially crucial when considering whether LOD should only be permitted when no organs donated post-mortem are available for transplantation in reasonable time.

67 Ibid.
69 German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 76; Kruse (1986), p. 257.
70 Papachristou et al., Vol. 78 Transplantation 1506, 1509 (2004); Walter et al., Vol. 11 Medical Science Monitor 503, 504 (2005).
71 These rights are, e. g., included in the Charter of Fundamental Rights of the European Union.
72 Information from T. Gutmann.
73 Ibid.
Second, we consider the relation between LOD and alternative therapies. Specifically, we discuss whether LOD should only be allowed if all other possible therapies are exhausted. Proponents of the subsidiary principle are typically in favour of restricting LOD to specified LOD, or even to direct LOD.

The principle of subsidiarity is often justified by the potential living donors’ need for protection.

The principle of subsidiarity is also subject to severe critique, though. One critique of the principle of subsidiarity is that it jumbles the macro- and the micro-level. 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 the micro-level inter alia. 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. 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.

To use the principle of subsidiarity as an argument to restrict LOD and to prohibit unspecified LOD is just as incomprehensible as all other approaches connected to the principle of nonmaleficence.

2 Lack of Voluntariness

If a normative concept of LOD is primarily based upon the principle of respect for autonomous choices, then a lack of voluntariness is the worst case.

Therefore, all countries require the donor to act voluntarily. None of the national laws contain a definition of the term voluntariness and no consensus on a definition of the term exists. According to Beauchamp and Childress, “a person acts voluntarily to the degree that he or she wills the action without being under the control of another’s influence.” Applying this to LOD means that the donor must not be exposed to any force or coercion (or fraudulent misrepresentation). She must come to an autonomous decision, and she must have the opportunity to comprehend that she can choose between two alternatives, and that she can act according to her will.

After introducing voluntariness in general, we (1) address the connection between the donor-recipient relationship and voluntariness and (2) gender related issues of voluntariness.

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76 Gutmann/Schroth (2002), p. 76.
77 Cf. German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 77.
78 German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 77; Gubernatis (2002).
83 Information from T. Gutmann.
2.1 Connection between donor-recipient relationships and involuntariness

Some argue that related LOD is specifically haunted by the danger of involuntary decisions, while others claim that unrelated LOD is connected to involuntariness.

Some believe that there is a factual connection between related LOD and involuntariness. Several academics state that the donor might be pressured within the family. A survey conducted on living parental liver donation concluded that the parent’s decision in favour of donating part of their liver to their child could not be called a free choice in the sense of a choice made willingly and easily. In contrast, others assert that if family members are thought of as non-autonomous donors, the notion of voluntariness is distorted, as it conflates hard choices with involuntary ones. There is no reason to assume that critical decisions which don’t seem to have an alternative lack voluntariness. Not being able to help a loved one could also be in contrast to the potential donor’s interest. However, that pressure in families might exist cannot be denied. Careful screening procedures must be utilized to ensure that relatives really act voluntarily.

In contradiction to the previous opinion, some argue that there is a factual connection between unrelated LOD and involuntariness. The German Bundestag justified the restriction of the donor-recipient relationship by stating that, in general, only a family relationship or another close personal relationship guarantees voluntariness in LOD. Some (strangely) claim that LOD to a stranger can be considered a supererogatory action, its exercise being an indication of involuntariness or a lack of competence.

On the other hand, social research demonstrates that organ donors with a competent, informed and voluntary decision to act altruistically towards strangers can be found in great numbers. Furthermore, in comparison to related LOD, pressure or coercion from a family member does not have to be feared in case of unrelated LOD.

That some experts believe related LOD is especially connected to involuntariness, while others believe unrelated LOD is connected to involuntariness, shows that there might be something wrong with both arguments. In both cases, involuntary decisions are possible, but both types of LOD also contain cases that are the result of a voluntary, well informed decision. Hence, an evaluation of each individual case is preferable.

91 Forsberg et al., Vol. 8 Pediatric Transplantation 372, 374 (2004).
94 Bundestag printed paper 13/4355 (1996), p. 20; see also German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 3b.
2.2 Gender related issues of voluntariness

In Europe, there is a gender bias with regard to the amount of LODs being performed. 2 out of 3 kidneys are donated by women, and the majority of LOD recipients are men.99

The following table shows the situation in the United Kingdom as an example:100

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrelated living kidney donation from 2000–2007</td>
<td>565 (61 %)</td>
<td>355 (39 %)</td>
</tr>
<tr>
<td>Related living kidney donation from 2000–2007</td>
<td>1172 (52 %)</td>
<td>1072 (48 %)</td>
</tr>
<tr>
<td>Recipients of unrelated living kidney donation</td>
<td>324 (35 %)</td>
<td>596 (65 %)</td>
</tr>
<tr>
<td>Recipients of related living kidney donation</td>
<td>929 (41 %)</td>
<td>1315 (59 %)</td>
</tr>
</tbody>
</table>

Different reasons are mentioned for this imbalance, although no clear explanation exists. First, societies that are characterised by a high degree of male dominance are referred to. Men are still, for the most part, the breadwinners in the family. Hence, a downtime, as a result of the LOD, is expected of women more often than of men.101 However, given the social facts concerning the labour market, it may also be a perfectly rational choice for a wife to donate for a family member instead of letting her husband do it. Second, women might feel more pressure than men.102 Third, some assume that women have a more altruistic attitude.103 However, a prospective German study showed that (in contrast to mothers who gave an organ to their child) wives who acted as organ donors for their husbands primarily followed reasonable self-serving motives: their aim was to get their ‘functioning’ partner back.104 Fourth, men suffer more often from hypertension and coronary artery disease, leading to their exclusion as donors.105 Also, more men suffer from end-stage renal disease and diabetes than women,106 and are consequently in need of a donor organ. From a medical point of view, it is easy to see why more women become living organ donors.108 In conclusion, as long as every single act of LOD is justified in itself, the donor’s gender seems morally irrelevant.

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100 Fuggle et al., Vol. 89 Transplantation 694, 696 (2010). More recent statistics for unspecified LOD are different, though, since from July 2007 until July 2011, 59 % of the donors of unspecified LOD were male (Cronin, Vol. 343 British Medical Journal (2011); NHS Blood and Transplant (2010)).
108 Information from C. Rudge.
3 The Social Pressure Argument

(1) Due to the fact that LOD is the only option for several sick patients because of the severe organ shortage, potential living donors are already under pressure.

(2) Afterwards, we analyse the complex interactions between donor and recipient.

(3) Finally, we mention the donor and recipient’s social environment.

3.1 Organ shortage increases the pressure on all potential living organ donors

Because of the severe organ shortage, the more people that get the legal chance to become a living donor means that more people will face the burden of deciding whether to donate or not.\textsuperscript{109} The German Bundestag’s Parliamentary Commission consequently drew the conclusion that LOD should be restricted to a minimum and that paired donations and unspecified LOD should remain prohibited.\textsuperscript{110}

The rationale of this argument, that it is more important for the state to protect its citizens from having to face hard choices than to give them the chance to choose whether to help or even save a person in need, is startling. It presents a degrading image of citizens who are incapable of deciding for themselves in critical situations. It cannot even be justified paternalistically, because it is clearly not in the best interest of competent adults to be generally withheld the chance to save a (close) person in need.\textsuperscript{111} In addition, allowing unspecified LOD cannot be equated with the duty to actually do so.

3.2 Interactions between donor and recipient

The potential donor’s refusal to donate might cause nasty effects on the relationship and might lead to a painful sense of guilt and failure.\textsuperscript{112} If the donor consents, in contrast, this might cause the potential recipient to worry about the donor’s health or to wonder why the donor is offering such a noble gift.\textsuperscript{113} After the LOD, a failure might demoralise the donor,\textsuperscript{114} or the recipient might be afraid of disappointing the donor.\textsuperscript{115} If the LOD is successful, the recipient often feels guilty that the donor had to undergo an operation,\textsuperscript{116} and he might have a persistent feeling of indebtedness to the donor.\textsuperscript{117}


\textsuperscript{110} Information from T. Gutmann.

\textsuperscript{111} Gutmann/Schroth (2002), p. 115.

\textsuperscript{112} Schneider (2004), \url{http://www.gen-ethisches-netzwerk.de/gid/163/mensch/schneider/lebendspende-kommerzialisierung-des-unbezahlbaren}.


\textsuperscript{114} Virzì et al., Vol. 39 Transplantation Proceedings 1791, 1793 (2007).


\textsuperscript{116} Forsberg et al., Vol. 8 Pediatric Transplantation 372, 372 (2004).

3.3 Social environment

If donor and recipient are related, they mainly have the same social environment. This usually leads family and friends to approve of the LOD.\textsuperscript{118} In contrast, unspecified LOD’s are usually disliked by family and friends of the donor. They do not understand why their relative intends to risk his life for a stranger.\textsuperscript{119}

4 Unspecified living organ donation and cross-over living organ donation lead to organ trade

Some state that unspecified LOD and cross-over LOD lead to organ trade. The German Federal Constitutional Court states that the German legislator is right to assume that banning unspecified LOD is necessary to prevent organ trade.\textsuperscript{120} However, the danger that unspecified LOD might cause commercialisation and organ trade can be nipped in the bud if the donation occurs within a pool of organs that is handled by a neutral agency, which coordinates the organ transplantation, organ allocation and maintains the anonymity of the donor.\textsuperscript{121}

With respect to cross-over LOD, a German parliamentary commission stated that “[a]llowing [it] leads to the danger of [covert commercial] brokers and of trading in organs.”\textsuperscript{122} Opponents argue that the danger of organ trade is not present in cases of cross-over LOD, or that the danger is at least not higher than in cases of direct LOD,\textsuperscript{123} since every donor only donates to help a person she is related to.\textsuperscript{124}

5 Justice and equality

A thorough examination of the philosophical debate on the notions of justice and equality is beyond the scope of this chapter. (1) We only examine whether LOD in general can be judged to be just and equal and (2) whether justice and equality can be answered in the affirmative with regard to certain groups of potential living donors and models of donation.

5.1 Justice and equality of living organ donation in general

A few critics of LOD claim that it is an unfair procedure in general because not all patients have a potential living organ donor.\textsuperscript{125} However, even if not every person suffering from organ failure knows a living person as donor, each LOD still benefits all people waiting for an organ. If fewer


\textsuperscript{119} Massey et al., Vol. 10 American Journal of Transplantation 1445, 1450 (2010); Matas, in Gutmann et al. (ed.) (2004), p. 199.

\textsuperscript{120} Cf. Evans, Vol. 15 Journal of Medical Ethics 17, 18, (1989); German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 3b.


\textsuperscript{122} Bundestag printed paper 15/5050 (2005), p. 42 & 73 f.

\textsuperscript{123} Hohmann (2003), p. 86.


\textsuperscript{125} Cf. Bakker, in Price/Akveld (ed.) (1997), p. 29, who also states right away that it seems very unlikely that a surgeon would condemn a patient on the waiting list when he has the option for a LOD; German Association of Dialysis Patients’ motion before the German Court of Constitution, 1999; cf. Hilhorst, Vol. 8 Ethical Theory and Moral Practice 197, 201 (2005).
people are in need of a donor organ, then the waiting time for all patients on the waiting list will be shortened.\textsuperscript{126}

5.2 **Justice and equality with regard to certain groups of potential donors**

We will consider whether the situation of LOD is unjust or unequal for (1) women and (2) minorities.

1) **If more women** become living organ donors than men because they are being exploited to a certain extent, this has to be abolished. If that is not the case, the difference does not seem problematic.\textsuperscript{127} People who are willing to donate should not be kept from doing it if they act voluntarily and if all other requirements are fulfilled. An “equitable donor-recipient-ratio in living organ donation”\textsuperscript{128} is no important goal in itself.

(2) The situation of LOD is rather unjust and unequal for **minorities**.\textsuperscript{129} In the United Kingdom, e.g., almost 1 in 4 patients who are waiting for a kidney transplant are from a minority ethnic group.\textsuperscript{130} The main reasons seem to be a less advanced education and the lower income of minority ethnic communities.\textsuperscript{131} Therefore, LOD awareness in the relevant communities should be raised,\textsuperscript{132} and effort should be made to increase the amount of organ donations from people that belong to minorities.\textsuperscript{133}

6 **Special groups of potential donors**

Most national transplant laws completely prohibit **minors** and **mentally incapacitated adults** from acting as living organ donors, not all though.

LODs by minors for the benefit of family members have been executed successfully, but remain controversial. LOD for family members might increase the **pressure** placed on the potential donors.\textsuperscript{134} Most assume that a competent adult can handle the pressure better than a more immature person.\textsuperscript{135}

The opposing view argues that there might be cases in which the organ removal of a minor is ethically justifiable. Cases are imaginable in which a prohibition to donate affects the minor more negatively than being allowed to donate.\textsuperscript{136}

Unspecified LOD by minors and mentally incapacitated adults is not even considered.

\textsuperscript{127} P. 16 f.
\textsuperscript{128} Biller-Andorno, Vol. 5 Medicine, Health Care and Philosophy 199 (2002).
\textsuperscript{132} Ismail et al., Vol. 14 Medicine, Health Care and Philosophy (2011).
\textsuperscript{134} Cf. Gutmann, in Schroth et al. (ed.) (2005), Sec. 8, at 7; Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 145.
7 Arguments against specific methods and programmes to increase living organ donation

There are different types of LOD.\textsuperscript{137}

(1) We start with a discussion of those types of LOD that involve more than one donor-recipient pair.

(2) Afterwards, we present the types of LOD that involve the donation to an anonymous recipient/stranger (as opposed to direct donation).

(3) Lastly, we introduce the type of LOD that connects LOD with post-mortem organ donation.

7.1 Living organ donations that involve more than one donor-recipient pair

(1) We present specific arguments concerning cross-over LOD.

(2) We analyse unbalanced living paired exchange and living paired cascade exchange.

7.1.1 Cross-over living organ donation

A cross-over donation takes place if a willing person cannot donate an organ to her partner due to immunological reasons and another donor-recipient pair has the same problem. If medically possible, the two recipients can swap places. Recipient A gets the organ from the partner of recipient B, while, in exchange, recipient B receives the organ from donor A. This procedure then allows for two medically incompatible pairs to be converted into two medically compatible pairs.\textsuperscript{138}

One main concern is that the pressure on the potential donor might be higher in cross-over LOD than it is in a direct LOD because the medical borders that possibly eliminate a particular LOD are inapplicable.\textsuperscript{139} Also, if the LOD fails, the donor of a direct LOD at least knows that she did everything in her power to help the sick person. In cross-over LOD, this psychological benefit might be more diffused.\textsuperscript{140} Or, if the success of the two executed transplantations is different, this might cause a feeling of inequality.\textsuperscript{141} Finally, it is a high psychological burden for the organ recipient to ask a relative for a donation, but it may be even more demanding to ask the relative to take part in a cross-over LOD.\textsuperscript{142}

There are good counter-arguments to the criticism. The expected benefit that causes the donor’s willingness to donate is the same for direct LOD and cross-over LOD.\textsuperscript{143} Cross-over LOD rules out a potential medical excuse if the donor and recipient are medically incompatible. One

\textsuperscript{137} This has already been made clear above.


should assume that potential donors want to be suitable, not that they are hoping for a medical excuse in such a case.\textsuperscript{144}

### 7.1.2 Unbalanced living paired exchange

In unbalanced living paired exchanges, one donor-recipient pair in which the donor has blood type 0 is asked to participate in an exchange, even though he has the possibility to donate directly to his related recipient.\textsuperscript{145} One donor-recipient pair does not have the possibility for a direct LOD, while the other pair does have this option and would not have to take part in the exchange to realise their intended LOD.\textsuperscript{146}

Those who argue against this type of LOD claim that the potential donor with blood type 0 might feel \textit{pressured} to take part in the unbalanced living paired exchange.\textsuperscript{147} To do so would not be in accord with his initial plan to donate directly to his relative\textsuperscript{148} and recipient A might prefer to receive the kidney directly from his relative.\textsuperscript{149}

Unbalanced living paired exchange, in contrast to several other exchange programmes, \textit{considers the difficulties blood type 0 recipients have}.\textsuperscript{150} Also, even though donor A is asked to participate in this type of LOD, he has the option of saying “No.” A mere question cannot be equated with force. The donor might even be thrilled to make two transplantations possible.

### 7.1.3 Living paired cascade exchange

Living paired cascade exchanges are LODs that consist of more than two donor-recipient pairs. Every intended recipient in the exchange gets an organ from a compatible donor who is also involved in the exchange.\textsuperscript{151} The amount of involved couples and the amount of exchanges is variable.

As a result, some fear that the \textit{comprehensibility} maybe lost.\textsuperscript{152} Additionally, \textit{immunological compatibility} could, at some point in the future, become unnecessary for organ transplantation, making living paired cascade exchanges useless.\textsuperscript{153}

Living paired cascade exchange is also supported. It can \textit{overcome the inability} of a willing donor to actually donate to a specified recipient.\textsuperscript{154} The reference to \textit{potential improvements in the future} is criticised because future improvements are uncertain and do not help patients who need help immediately.\textsuperscript{155} In addition, the donor involved in a living paired cascade exchange has the intention to help a relative. This is used as justification for direct LOD and should therefore apply to living paired cascade exchange as well.\textsuperscript{156}

\textsuperscript{145} Donors with blood type 0 are universal donors and can donate to their intended recipient, no matter whether he has blood type A, B or AB if there is no positive cross-match (Ross, Vol. 16 Kennedy Institute of Ethics Journal 151, 159 (2006)).
\textsuperscript{146} Ross, Vol. 16 Kennedy Institute of Ethics Journal 151, 155 f. (2006).
\textsuperscript{148} Bundestag printed paper 15/5050 (2005), p. 47.
\textsuperscript{149} Ross, in Weimar/Bos/Busschbach (ed.) (2008), p.186.
\textsuperscript{150} Fortin et al., in Weimar/Bos/Busschbach (ed.) (2011), p. 422.
\textsuperscript{151} Ross, Vol. 16 Kennedy Institute of Ethics Journal 151, 154 (2006).
\textsuperscript{152} Bundestag printed paper 15/5050 (2005), p. 42.
\textsuperscript{153} Cf. Riedel, in Rittner/Paul (ed.) (2005), p. 75.
\textsuperscript{155} Gutmann (2006), p. 38.
\textsuperscript{156} Patel/Chadha/Papalois, Vol. 3 Experimental and Clinical Transplantation 181, 184 (2011).
7.2 Living organ donations that involve the donation to an anonymous recipient

In this section, we present
(1) unspecified LOD and
(2) pool donation.
(3) We introduce directed altruistic LOD and
(4) analyse unspecified non-directed donation catalysing cascade exchanges.

7.2.1 Unspecified living organ donation

Several national transplant laws require a genetic or emotional relationship between donor and recipient (or some form of close connection). An unspecified LOD describes cases where a person decides to donate an organ to an anonymous and unspecified recipient: a living person donates an organ to a stranger.

Scepticism towards unspecified LOD exists. Experts fear that the decision to donate to a stranger is based on an excessive helper syndrome or on psychopathological reasons. Moreover, many doubt that the amount of people actually performing such a donation would increase if unspecified LOD were allowed.

With respect to the scepticism towards unspecified LOD, empirical evidence shows that people who perform an unspecified LOD are “very self-directed and without psychopathology.” The argument that unspecified LOD would not significantly raise the amount of donor organs available is refuted by stating that unspecified LOD might indeed make up a major source for donor organs in the future.

7.2.2 Pool donation

Pool donation means that a living donor gives an organ to a pool of organs and her relative receives a compatible organ from the pool in return.

Some doubt that this would actually increase the amount of donor organs. How big the pool would have to be to actually increase the amount of donor organs is also unclear. In addition, the potential increase of pressure on potential donors is referred to, because this type of LOD makes it difficult for a potential donor to decline.

In favour of this method, one could claim that the amount of possible transplantations increases.

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157 Dor et al., 2011 Transplantation 1 f.
7.2.3 Directed altruistic living organ donation

The donor in directed altruistic LOD is a person who donates an organ to an anonymous recipient, but the recipient either has to meet specific criteria, e.g., regarding age, ethnicity, or is a specific individual, such as a famous person.\textsuperscript{166} This type of LOD is considered to be discriminatory.\textsuperscript{167} It usually comes up when a person hears about a patient, often a public figure, in the media. According to the Committee of the Dutch Health Council, this could dangerously lead to the potential donor acting impulsively to help a celebrity and it might be unfair to receive an organ just because of fame.\textsuperscript{168} Furthermore, a person who consents to deceased donation cannot indicate a preference to donate to a specific group of persons or one particular person.\textsuperscript{169} Prohibiting this type of LOD would prevent a sick person from getting the help he needs, thus interfering with the recipient’s fundamental rights.\textsuperscript{170} Prohibiting altruistic directed LOD would additionally disrespect a donor’s autonomy.\textsuperscript{171} One must also consider that the particular LOD might only happen because of a felt, special relationship to the group. Respecting this identity provides the basis for forms of directed donation that are partial, but fair and justified.\textsuperscript{172} The particular LOD might not take place at all without the mentioned relationship,\textsuperscript{173} and therefore it does not disadvantage anyone.\textsuperscript{174} Allowing the LOD, on the other hand, could even cause all other patients on the waiting list to move up because the selected person would be removed from the waiting list.\textsuperscript{175} Because of the severe shortage of donor organs, willing donors should not be turned away.\textsuperscript{176} The comparison of LOD and post-mortem organ donation is criticised as well because the regular case for LOD, in contrast to deceased donation, is to be directed.\textsuperscript{177}

7.2.4 Unspecified non-directed donation catalysing cascade exchanges

Unspecified non-directed donation catalysing cascade exchanges describe a living organ donor who performs an unspecified LOD and catalyses a cascade of LODs. It ends with a living donor donating an organ to the deceased donor waiting list.\textsuperscript{178} It, therefore, connects unspecified LOD and the participation of more than one donor-recipient pair.


\textsuperscript{168} The view of the Committee of the Dutch Health Council is stated in Hilhorst, Vol. 8 Ethical Theory and Moral Practice 197, 199 (2005).

\textsuperscript{169} Ibid., p. 201.

\textsuperscript{170} Gutmann (2006), p. 45.


\textsuperscript{172} Hilhorst, Vol. 8 Ethical Theory and Moral Practice 197, 205 f. (2005).

\textsuperscript{173} Ibid., p. 205.


\textsuperscript{175} Veatch, Vol. 23 Journal of Medicine and Philosophy 456, 462 (1998) (with regard to directed deceased donation).


Unspecified non-directed donation catalysing cascade exchanges are criticised with respect to blood group equity because, in more than 2/3 of the incompatible cases the recipient has blood type 0. If the patient has blood type 0, she needs a donor with this blood type as well. If the intended donor does not have this blood type, an exchange is seldom because donors with blood type 0 are universal donors. It is, therefore, e. g., problematic if the unspecified living organ donor is of blood type 0, while the cascade results in a blood type A organ going to the waiting list. That leads to a further disadvantage for patients on the waiting list with blood type 0. That is inconsistent with the main idea of the Rawlsian Theory of Justice which permits inequity only if it benefits those who are worst off.

In contrast, such a programme makes a large number of transplantations possible and reduces the number of patients on the waiting list. It can also be assumed that donating within this scheme is in the interest of the unspecified living organ donor because such participation increases the probability of a good result. With regard to the Rawlsian Theory of Justice, Gutmann argues that only duties to support disadvantaged groups can be deduced from this consideration. The Rawlsian Theory of Justice does not, however, create a duty to establish general paternalistic measures that prevent other people from exercising their right of self-determination in a sufficient way. Gutmann’s argument would not speak against this type of LOD, but rather in favour of a duty to support patients with blood type 0.

7.3 Connection of living organ donation and post-mortem organ donation: List-paired exchange

List-paired exchange involves a living donor-recipient pair, a deceased donor and a candidate on the waiting list. The living donor donates to a patient on the waiting list. Afterwards, the recipient related to the living donor is given the highest priority to receive a compatible organ donated post-mortem.

The main concern related to this type of LOD is that it might be unfair because patients on the waiting list with blood type 0 are disadvantaged.\(^{191}\) This is inconsistent with the Rawlsian Theory of Justice.\(^{192}\) In addition, some claim that the order of the waiting list is disregarded (queue jumping) because the person who has an incompatible willing living donor moves to the top of the waiting list,\(^{193}\) and the person who was on top of the waiting list before moves back.\(^{194}\) Beyond that, an increase of pressure is feared.\(^{195}\)

One consequence of the arguments against list-paired exchange would be to prohibit it. With regard to the argument that it disadvantages recipients with blood type 0 who do not have a willing living donor,\(^{196}\) some suggest that this type of LOD only needs to be prohibited if blood type 0 recipients are involved.\(^{197}\)

Those in favour of list-paired exchange state that it would make LOD available when the willing donor is not able to donate directly to his relative and no match can be found in the cross-over programme.\(^{198}\) Also, the willing living donor and the patient on the waiting list profit from the donation.\(^{199}\) From a utilitarian point of view, this maximises the overall utility\(^{200}\) because the overall amount of donor organs available would be increased.\(^{201}\)

The different types of LOD are criticised, but also supported. The danger of increasing pressure on the potential donor is a recurrent argument against almost all different types of LOD. Pressure might exist, but no empirical evidence exists that proves that pressure would actually be more intense in cases of special types of LOD in comparison to direct LOD. The principle of respect for autonomy is mentioned in contrast. The donor’s wishes, as long as he is competent to consent, has done so voluntarily, has been informed properly and understands what he has been told, should be respected.\(^{202}\) Apart from this, the implementation of several types of LOD grants more people the opportunity to become a living organ donor. In times of severe organ shortage, (unnecessary) restrictions of LOD cannot remain unquestioned.\(^{203}\)

7.4 Result

The different types of LOD that can either be classified as indirect LOD or as unspecified LOD have now been introduced. All types of LOD have the positive effect of overcoming incompatibility between the willing donor and the intended recipient, increasing the amount of donor organs. The various types are also criticised, though. Most fear that the pressure inflicted upon the potential

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\(^{195}\) Bundestag printed paper 15/5050 (2005), p. 48.


donor might increase. Overall, with respect to cross-over LOD, living paired cascade exchange, unspecified LOD and pool donation, the advantages seem to outweigh the disadvantages. Unbalanced living paired exchanges, directed altruistic LOD, unspecified non-directed donation catalysing cascade exchanges and list-paired exchanges, in contrast, seem to be rather problematic, although there is hardly a reason for legally banning them.

8 Procedures

It is not uncommon for countries to establish procedural safeguards for LOD. Those that can be considered as restricting LOD to a certain extent will be considered here.

Switzerland does not restrict the donor-recipient relationship. Also, it has not established a state commission to review LOD. At the ELPAT Working Group Meeting Legal Boundaries in Berlin, the situation in Switzerland was discussed. In Switzerland, the situation for physicians is exceptional insofar as there is a very high level of trust in them; they believe their physicians will make good decisions. However, the Swiss Federal Act on the Transplantation of Organs, Tissues and Cells stipulates that “[a]ny person who removes organs […] must notify the Federal Office of this.”204 In addition, the hospitals and transplant centres themselves decide on specific procedures for LOD. In the United Kingdom, Sec. 33 Human Tissue Act 2004 standardises a criminal prohibition with a reservation to grant permission.205 The donor-recipient relationship is not restricted by law. In contrast to Switzerland, every LOD has to be approved by the Human Tissue Authority through an independent assessment process.206 The exact procedure depends on whether donor and recipient are genetically or emotionally related or if neither is.207 Thus, the types of LOD are treated differently in the United Kingdom.208 Another difference between the procedure in Switzerland and the United Kingdom is that “[a]ny person that removes organs” is addressed in Switzerland, while the members of the Human Tissue Authority in the United Kingdom are appointed by the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department.209 Hence, a state commission becomes involved in the United Kingdom. In Germany, the donor-recipient relationship is restricted by law. In addition, a commission has to give an opinion of whether there are substantiated reasons to assume that the donor’s consent is not being given freely or that the organ is the object of prohibited organ trade.210 It is governmental, but the commissions are “responsible according to Land legislation.”211

All in all, several countries have not only established material restrictions in LOD, but also restrictions on a procedural level.

IV Summary

First, LOD could be seen as a violation of the principle of nonmaleficence. Against this, the principle of autonomy, according to which every person has a right of self-determination, is mentioned. It even protects behaviour that might not be understandable for others, e. g., unspecified LOD. The right of self-determination is ensured by the patient’s informed consent, necessary for LOD in all

204 Art. 14 1 Federal Act on the Transplantation of Organs, Tissues and Cells.
206 Sec. 13 ff. Human Tissue Act; information from D. Price.
208 This is criticised by Choudhry et al., Vol. 29 Journal of Medical Ethics 169, 2003.
210 Sec. 8 III 2 Act on the Donation, Removal and Transplantation of Organs.
211 Ibid.
countries. Several countries even consider informed consent as sufficient to justify LOD, but not all. Even if informed consent is provided, LOD is not legal in case it would end the donor's life or would be directly life-threatening. Several countries additionally declare consent that would be against ‘good morals’ void. Arguing that only direct LOD should be permitted because the risks of LOD are too high is incorrect since the risks for all types of LOD are equal. In favour of restricting the donor-recipient relationship, some claim that unrelated donors do not benefit as much from LOD as related donors, and also that the special relationship between donor and recipient exclusively justifies LOD. But even though special responsibilities do exist in close personal relationships, this does not mean that these special responsibilities should be the only normative foundation of LOD. The most relevant aspect of any LOD is that the donor cares for the needs of others. This applies to all LOD, regardless of the relatedness of donor and recipient.

Second, there is no common opinion on the connection between related LOD and involuntariness, or unrelated LOD and involuntariness. With respect to any type of LOD, involuntary decisions might occur, but, in contrast, every type of LOD might contain cases that are the result of a voluntary decision. The best approach, therefore, is to judge each case individually and not simply prohibit certain donor-recipient relationships. Besides, several reasons for why more women act as living organ donors and more men act as recipients have been listed. As long as every LOD is justified in itself, the gender bias is irrelevant and a gender imbalance cannot be considered as malum in se.

Third, some are concerned that a general legalisation of LOD would increase the pressure on living individuals. The rationale of this – that it is more important for the state to protect its citizens from having to face hard choices than to give them the chance to choose whether to help or even save a person in need – is unsound.

Fourth, the association between unspecified LOD and cross-over LOD with organ trade is unwarranted.

Fifth, we considered whether LOD is just and equal. Some question the fairness of LOD, since it is not available to every patient in need. The solution, to prohibit LOD in general, would have a negative impact on both the patients who already have a living organ donor and those who are on the waiting list (each LOD shortens the waiting list, thus benefiting all candidates). The existing gender inequality is problematic only if it is based upon an exploitation of women. With respect to the fact that people from minority groups act less often as living organ donors and also profit less from LOD, an effort should be made to increase the amount of organ donations from people that belong to minorities.

Sixth, several arguments in favour of completely prohibiting minors and mentally incapacitated adults from acting as living organ donors exist. However, there are also valid arguments against a complete prohibition.

Seventh, the several different types of LOD have the positive effect of overcoming incompatibility between the willing donor and the intended recipient, increasing the amount of donor organs. In contrast, most fear that the pressure inflicted upon the potential donor might increase.

Eighth, several countries do not restrict the donor-recipient relationship, but do have specific procedures that must be followed.

With the exception of specific arguments concerning special models of LOD exchanges, none of the arguments brought forth for the necessity and the legitimacy of most of the legal restrictions proposed for LOD seems cogent.212 There is no class of donors and no category of LOD that should

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be generally dismissed by law. Rather, the solution seems to be a procedural one. Careful case-by-case decisions should be made.213

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I Introduction

There are not enough donor organs available to help all patients suffering from organ failure. Especially concerning LOD, there are, however, also legal reasons for this shortage. As we have already clarified in chapter 4, LOD regimes create, in part, an artificial scarcity and an appropriate legal framework for LOD, one without unjustified legal barriers and misguided rationales, must be estab-

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1 This article is the short version of the first and third articles of three articles that are written within the Project Living Organ Donation in Europe (EULOD). For a more detailed account, the author’s book Regulations regarding living organ donation in Europe – Possibilities of Harmonisation published by Springer may be consulted. The research leading to these results has received funding from the European Commission Seventh Framework Programme (FP7/2010-2012) under Grant Agreement 242177 Living Donation (EULOD Project). The author thanks Bijan Fateh-Moghadam and Thomas Gutmann for their guidance and the members of the ESOT/ELPAT Working Group on Legal Boundaries for their helpful comments. The first concept of this article has been developed by the author, Bijan Fateh-Moghadam, Thomas Gutmann, Assya Pascalev and Mihaela Frunza at a Workshop at the Centre for Advanced Study in Bioethics at the University of Muenster in July 2011.

lished. It therefore makes sense to analyse which LOD regulations are optimal. While doing so, we will consider the current national laws on LOD.

Seven central issues connected to LOD must be addressed.

(1) We regard the concept widely known as informed consent\(^3\) in detail in a few countries. Afterwards, we observe the different regulations for informed consent.

(2) We address the suitability of the transplantation.

(3) We describe to what extent minors and mentally incapacitated adults are allowed to become living organ donors.

(4) We address whether the donor-recipient relationship should be restricted.

(5) We illustrate the principle of subsidiarity.

(6) We examine several procedural issues.

(7) We present the social security regulations for donors in selected countries.

This report shows that some of the central issues of LOD are regulated homogeneously, while other central issues are regulated differently. There are compelling reasons to level these differences and to aim at a common European policy for LOD. The Member States of the European Union continually grow together and the level of cooperation between them steadily increases. This development can also be observed in the field of organ transplantation.\(^4\) European citizens in need of organ transplantation should have equal access to LOD if it is in accordance with justified legal and ethical principles. A harmonisation is, therefore, desirable and possible (the Common Frame of Reference for European private law\(^5\) is a fitting example of the harmonisation of European law).

This article considers all Member States of the European Union, along with Moldova, Norway and Switzerland. Almost all of these countries have established specific transplant laws. Austria, where the Position Paper passed by the Austria Health Limited Liability Company reflects common medical practice, is an exception.\(^6\) Ireland is also an exception. It has only established a Guide to Professional Conduct and Ethics for Registered Medical Practitioners.\(^7\) In addition, other national laws that influence the legal and practical situation are taken into account. The legal situation of Cyprus, Luxembourg and Malta is unclear.

## II Procedure to develop a best practice proposal

When aiming at harmonisation, one must not forget the diverse cultural backgrounds and legal systems.\(^8\) LOD is embedded in national legal systems with different legal traditions, regulatory techniques, leading principles and case law. However, a common aim is possible even if different methods, approaches and regulatory techniques are being used.

But not only comparative law gives reasons to expect that there may be different, yet equally functional legal means to serve the end of a justified CFR-LOD. The same follows from what Mar-

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\(^5\) See www.copecl.org.

\(^6\) Information from K. Bruckmueller.

\(^7\) Information from D. Madden.

marm calls the “unwritten rules of cross-national policy analysis” in medical care. Furthermore, the problems associated with simple forms of legal or policy transplantation in order to avoid gross mistakes in the use of comparative policy analysis, we must not believe in the “naive” transplantation conception of cross-national learning.” This tells us to search “widely for ‘best practices’” and to assume, “if found, they can be transplanted without loss from site A to site B. […] There is plenty of this about in the professional literature, but no social science support for the claim that a practice in one site can be transplanted without adaptation.” As there is a legal path dependency, there are also formative factors for policy making in each country, including the legacies of past policy on institutional features. Nevertheless, there is no reason to believe that different legal and/or policy systems cannot learn from one another.

In chapter 4, we analysed the arguments for the necessity and legitimacy of legal restrictions on LOD. Our next aim is to establish a Best Practice Proposal: Legal Safeguards For Living Organ Donation in Europe while considering the current national regulations for LOD. Following the Introduction to the Principles of European Contract Law, we will try “to establish those principles which [are] believed to be best under the existing economic and social conditions in Europe.”

In our case, however, we will consider the existing structures in national medical care systems as well. We present a short summary of the various national regulations on each issue and evaluate the different possibilities available to regulate these issues. The evaluation undertaken here is based on the results concluded in chapter 4. In addition, we take into account common principles, especially those established in the Charter of Fundamental Rights of the European Union.

III Best Practice Proposal

The general attitude towards LOD is positive, for good reasons. Thus, those in favour of restricting LOD must be able to prove that the restriction is legitimate. In addition, since too few donor organs are available, any legal restrictions on LOD must be justified and any unjustified barriers to LOD should be removed. However, the main priority of a best practice proposal should be to respect the potential donor’s informed and voluntary choice and ensure his welfare.

Which of the existing regulations are optimal?
(1) We evaluate the different regulations with regard to consent and disclosure.
(2) We address the required suitability of the transplantation.
(3) The regulations with respect to minors and mentally incapacitated adults are considered.
(4) We revive our discussion of the appropriate amount of restriction on the donor-recipient relationship.
(5) We illustrate whether it would be preferable to consider LOD as a subsidiary option only.
(6) Several procedural issues are examined.
(7) We work out the optimal social security regulations for donors.

13 Fateh-Moghadam (2011), p. 1 ff.; With respect to indirect LOD and unspecified LOD, “the barriers reported most commonly were that these donations were illegal in the country or thought to be unethical and could not be justified” (EULOD WP 2 (2012), DOW: Deliverable 4, p. 12).
1 Informed Consent

The transplant laws of the Member States of the European Union are unanimous in their requirement for a donor's informed consent. Chapter 4 already showed that in England, France, Italy and Spain, the patient’s consent is necessary, but not sufficient to justify LOD. In **England**, Sec. 33 Human Tissue Act 2004 standardised a criminal prohibition with a reservation to grant permission. To justify LOD, the patient’s consent is necessary, but not sufficient and several legal requirements have to be fulfilled. In France, the person’s individual freedom is legally protected, but the “right for respect of the human body” exists as well. As a consequence, the patient’s consent is necessary, but is not sufficient. An additional authorisation by law is required. An authorisation that allows physicians to perform LOD has been established. In **Italy**, Art. 5 Civil Code determines that disposing of one’s own body is forbidden if the act can cause a permanent disability of the person, if the act breaks the law or if it causes a public order offence. Since living kidney donation is allowed by law under specific preconditions, an exception to Art. 5 Civil Code exists. In **Spain**, mere consent is not sufficient to preclude the physician’s liability for bodily harm. An established legal exception has to be fulfilled additionally. LOD is explicitly permitted as an exception.

In contrast, in Austria, Germany, the Netherlands and Switzerland, the patient’s consent is sufficient to justify LOD. In **Austria**, the patient’s autonomy is protected by the Convention for the Protection of Human Rights and Fundamental Freedoms. As a consequence, the patient’s consent is necessary and sufficient to justify LOD. In **Germany**, the constitutionally protected “right of personality” contains the “right to dispose of one’s own body.” Hence, the patient is free to either allow or decline therapeutic treatments according to his will. In the **Netherlands**, a person has the right of self-determination. The patient’s consent is valid if the patient was sufficiently informed. That also applies to LOD. The **Swiss Constitution** protects the right of self-determination. This includes the right to dispose of one’s own body.

This difference is rooted in the general national laws of the respective countries. The aim to legitimise LOD can thus be reached differently.

It is unquestionable that the requirement of informed consent has to be part of any transplantation law. However, how the details of this premise must be worked out is unclear. Consent and disclosure will be regarded separately in the following sections. Establishing two separate regula-

15 See e.g. Donnelly/Price (ed.) (1997), p. 35.
22 Information from I. Marino.
23 Art. 1 Legislation on Donation, Retrieval and Transplantation of Organs and Tissues.
28 Di Fabio, in Maunz/Dürig (ed.) (2010), Art. 2 at 204.
30 Information from M. Bos.
31 Ibid.
32 Art. 10 II Swiss Constitution.
tions is preferable to reducing both aspects to a single regulation. This makes the importance of the process of disclosure clear.

1.1 Consent

All national laws considered require the donor to give valid consent. Belgium, Bulgaria, Estonia, Finland, Germany, Norway, Slovakia and the United Kingdom even explicitly require this in their national transplant laws.

So, a best practice regulation must explicitly require the donor’s consent. The details of the requirement for valid consent partly differ in the countries considered, making individual evaluations necessary.

1.1.1 Capacity to consent

Consent can only be given by a competent individual. Belgium, the Czech Republic, Germany, Hungary, Lithuania, the Netherlands, Poland, Slovakia, Spain and Switzerland explicitly state this in their national transplant laws.

An adequate transplantation law should require the donor’s capacity to consent, but need not include a definition of competence since a definition is typically provided by the national legal systems.

35 Ibid.
36 Art. 5 Law on Retrieval and Transplantation of Organs.
38 Sec. 9 (1), 1) Transplantation of Organs and Tissues Act.
39 Sec. 2, 1 Act on the Medical Use of Human Organs and Tissues.
40 Sec. 8 (1) No. 1 b) Act on the Donation, Removal and Transplantation of Organs.
41 Sec. 1 Act relating to transplantation, hospital autopsy and the donation of bodies etc.
42 Sec. 36 (2) Act on Healthcare, Healthcare-Related Services and on the Amendment and Supplementing of Certain Laws.
45 Art. 9 Law on Retrieval and Transplantation of Organs.
46 Art. 3 (1) c) Transplantation Act on Donation, Removal and Transplantation of Organs and Tissue and on the Amendment of some Acts.
47 Sec. 8 l No. 1 a Act on the Donation, Removal and Transplantation of Organs.
48 Sec. 206 (1) Act on Health.
49 Art. 10, 2 Law on Donation and Transplantation of Human Tissues, Cells and Organs.
50 Sec. 3, 1 Organ Donation Act.
51 Art. 12, 1., 7 The Cell, Tissue and Organ Recovery, Storage and Transplantation Act.
52 Sec. 36 (2) Act on Healthcare, Healthcare-Related Services and on the Amendment and Supplementing of Certain Laws.
54 Art. 12, a) Federal Act on the Transplantation of Organs, Tissues and Cells.
1.1.2 Voluntariness of consent

The need for voluntary consent is expressed by all the countries considered. Gutmann, for example, considers the lack of a donor’s voluntariness to be the worst case in LOD (besides the donor’s death). Voluntariness must, consequently, be required in any adequate transplantation law. A detailed approach, however, to determine how to decide whether the donor’s decision was made voluntarily should not be included in the best practice proposal. This would make the best practice proposal too unwieldy and impracticable. It could, however, be mentioned in an explanatory report.

1.1.3 Formal requirements

The formal requirements for consent differ significantly throughout the countries considered. A best practice proposal should emphasise the necessity of an announcement and the insufficiency of internal consent. In addition, the donor should have enough time to reconsider his decision. After consent is given, he should therefore be granted an adequate period of time until the surgery actually takes place.

Are any additional formal requirements recommendable? One potentially important formal requirement is the donor’s written consent. Requiring consent to be in writing would be advantageous to the donor insofar as he can cogitate on his decision one more time. Furthermore, a written document would serve as evidence that consent has actually been given. To require the consent to be in writing cannot seriously be considered as making it (more) complicated for the donor to perform his right of self-determination. Also, consent has to be in writing in several countries; only Austria, Italy and the United Kingdom do not explicitly require a written consent. Written consent should, consequently, be required in an adequate transplantation law.

Belgium, Poland and Portugal request a witness to be present while the donor consents. Bulgaria, Hungary, Moldova, Portugal and Spain require the consent to be approved by a public authority.

Whether consent is to take place “before witnesses, […] before another person other than the physician performing the transplantation, before a public authority, or even with approval by a

55 Information from T. Gutmann.
63 Art. 2 Legislation on Donation, Retrieval and Transplantation of Organs and Tissues.
64 In the United Kingdom, it is considered good practice to obtain written consent for significant procedures such as organ donation, though (No. 58 Code of Practice 1).
65 Art. 8 Sec. 2, 1 Law on Retrieval and Transplantation of Organs.
66 Art. 12, 1, 7 Cell, Tissue and Organ Recovery, Storage and Transplantation Act.
67 Art. 8, 2 Law on Harvesting and Transplanting Human Organs and Tissues.
69 Sec. 209 (2) Act on Health.
72 Art. 4, c. Law Regulating Organ Recovery and Transplantation.
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1.1.4 Withdrawal of consent

Almost all countries allow the potential donor to withdraw his consent. Only the Latvian, Polish, Swedish, Moldovan and Swiss transplant law do not explicitly contain this option. The possibility of withdrawal of consent must be present at all times, and this must be explicitly mentioned in the best practice regulation. The donor must be informed about this option. The purpose of this is to guarantee the autonomy of the donor, who can potentially change her mind. It is also intended to limit or, at best, prevent the posterior regret of an organ removal.

1.1.5 Limitation of consent

An internationally agreed standard is that any LOD which ceases the donor’s life, or would be directly life-threatening, is illegal. Several countries additionally declare consent void if it goes against good morals. For example, the German Criminal Code states in Sec. 228, “Whoever commits bodily injury with the consent of the injured person only acts unlawfully if the act is, despite the consent, contrary to good morals.” Therefore, an action that is against good morals is punishable, even if the donor gave her consent. We find that defining further limitations in the best practice proposal is highly questionable. This issue was discussed, inter alia, at the 2011 ELPAT-Working Group on Legal Boundaries Conference in Berlin. The prevalent view was that no further limit on the legal ability of donors to give consent should be stipulated by law. This question should rather be considered on a case-by-case basis before determining whether the LOD will be performed. Thus, the only LODs that should be banned are those that would lead to the donor’s death or are directly life-threatening (although this ban usually follows from the general national laws already).

1.1.6 Consent of the recipient

Some countries also explicitly require the recipient to consent to the LOD, which is a measure taken to assure her autonomy. This requirement could be viewed as redundant because medical ethics already state that due to the right of autonomy, the recipient has the right to decline an organ, and that this right has to be enforced in any case. The Belgian situation can be used as a case in point. The Law on Retrieval and Transplantation of Organs does not provide any special regulation with regard to the consent of the recipient, but it must always be present anyway. This is because, in addition to the law that specifically concerns the procurement and transplantation of organs, the general law

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79 Merckx, Falcone Project, Belgium, p. 5.
applies. If one applies the common rights, any medical operation is an invasion of one’s physical integrity. The consent of the patient can justify this. Moreover, Art. 8 of the Belgian Law of 22 August 2002 expressively states that any patient has the right to freely consent to any operation once the preliminary information has been achieved.\textsuperscript{80} Several countries, in addition, mention exceptions to the requirement of “explicit consent” by the recipient. Explicit consent is commonly unnecessary if a delay in the performance of the procedure threatens the recipient’s life or if it is impossible to obtain her consent. Even if the national transplant law does not explicitly state an exception, the general legal system usually allows a decision based on substituted or presumed consent due to the state of emergency in cases where therapeutic treatment is needed. LOD is a therapeutic treatment for the organ recipient.\textsuperscript{81} Consequently, the possibilities of consenting on behalf of the incapacitated patient and replacing consent because a state of emergency exists (one which the European legal systems have in common), are valid with regard to the recipient.\textsuperscript{82}

The best practice proposal should demand that these principles be applied to ensure that the recipient’s consent is seen as necessary; but, the exceptions to these principles should also be obvious.

1.2 Disclosure

All countries considered require the potential donor to become sufficiently informed. This requirement, without doubt, has to be included in any adequate transplantation law. National provisions are not equal in depth. The aim of every disclosure should be to educate the person concerned so that she can come to a self-determined decision.\textsuperscript{83} Since the organ removal is a non-therapeutic treatment for the donor,\textsuperscript{84} who usually is a medically layperson,\textsuperscript{85} the requirements for the amount of information given to the donors should be very high.\textsuperscript{86}

1.2.1 Disclosure matters

The disclosure of LOD’s possible consequences, the medical background of the surgery, the protection of the donor and the impact on the recipient are referred to in several national transplant laws. The Belgian,\textsuperscript{87} Moldovan\textsuperscript{88} and Spanish\textsuperscript{89} laws, for example, explicitly refer to the physical, mental, familial and social consequences that have to be disclosed. In contrast, the Bulgarian,\textsuperscript{90} Estonian,\textsuperscript{91}...

\textsuperscript{80} Information from R. Willmotte.
\textsuperscript{82} Ibid.
\textsuperscript{83} Schroth, in Schroth et al. (ed.) (2006), p. 95.
\textsuperscript{87} Art. 9, 2 Law on Retrieval and Transplantation of Organs.
\textsuperscript{88} Art. 15 (3) Law on the Transplant of Human Organs, Tissues and Cells.
\textsuperscript{89} Art. 4, b. and Art.9, 3. Royal Decree 2070/1999.
\textsuperscript{90} Art. 24 (1) Law of the Transplantation of Organs, Tissues and Cells.
\textsuperscript{91} Sec. 6 (2) Transplantation of Organs and Tissues Act.
Italian,\textsuperscript{92} Latvian\textsuperscript{93}, Norwegian,\textsuperscript{94} Portuguese,\textsuperscript{95} Scottish\textsuperscript{96} and Slovakian\textsuperscript{97} laws do not highlight specific consequences, they only require the disclosure about consequences and risks in general. Since the donor will usually be a medical layperson, it can be presumed that he does not have any knowledge about the medical background of LOD. For that reason, many national laws, not nearly all though, require the information for the donor to contain a medical explanation, allowing him to learn about the medical procedure that takes place. The national laws that do so are very diverse with regard to their exact requirements and content.

It may seem sufficient to only require the donor to be informed extensively. However, an actual list of the aspects that have to be included in the donor’s disclosure would provide legal clarity and legal certainty.\textsuperscript{98} This is, therefore, preferable. The entire (medical) procedure should be explained to the donor.\textsuperscript{99} Furthermore, the risk of death must be disclosed\textsuperscript{100} as well as any known risks to the donor’s health relating to evidence-based data. Since LOD always involves two patients,\textsuperscript{101} the donor should be informed about alternative therapies for the recipient.\textsuperscript{102} In addition, the recipient’s prospect of success and risks should be disclosed to the donor. In a best practice regulation, the donor should be mandatorily informed about any additional, foreseeable circumstances that are relevant to her.\textsuperscript{103} One issue open to deliberation is whether the disclosure of the donor should be defined objectively or whether the exact content should be up to the person concerned. In favour of a subjective orientation, many claim that not every patient wants to be burdened with all the details.\textsuperscript{104} Others, in contrast, may require an in-depth understanding.\textsuperscript{105} An objective approach would provide legal certainty. It could, for example, prevent any conflicts that may arise post-LOD regarding the donor’s prior level of knowledge on the topic. It might also be difficult to accurately evaluate exactly what the donor wants to be informed about and what she might rather not want to know. Consequently, a best practice regulation should clearly present what the donor has to be informed about. The listings in Art. 9, Swiss \textit{Transplantation Ordinance} and Sec. 8 II German Act on the Donation, Removal and Transplantation of Organs can serve as examples.

1.2.2 Comprehension

Only a few national laws explicitly require the donor to understand the information. In Norway\textsuperscript{106} and Sweden,\textsuperscript{107} for example, the donor is required to understand the meaning of the information and, in order to assure this, the physician has to verify it.

\textsuperscript{92} Art. 2 Legislation on Donation, Retrieval and Transplantation of Organs and Tissues. 
\textsuperscript{93} Sec. 13 Law on the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine.
\textsuperscript{94} Sec. 1 Act relating to transplantation, hospital autopsis and the donation of bodies etc. 
\textsuperscript{95} Art. 7 Law on Harvesting and Transplanting Human Organs and Tissues. 
\textsuperscript{96} Reg. 2 (7) Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. 
\textsuperscript{97} Sec. 6 (1) Act on Healthcare, Healthcare-Related Services and on the Amendment and Supplementing of Certain Laws. 
\textsuperscript{99} See also Principle (23) Directive 2010/45/EU on Standards on Quality and Safety of Human Organs intended for Transplantation. 
\textsuperscript{101} Mehrabi et al., Vol. 81 Der Chirurg 794, 800 (2010); Schroth, in Schroth et al. (ed.) (2006), p. 97 f. 
\textsuperscript{102} Mehrabi et al., Vol. 81 Der Chirurg 794, 800 (2010). 
\textsuperscript{103} Schroth, in Schroth et al. (ed.) (2006), p. 98. 
\textsuperscript{105} Ibid. 
\textsuperscript{106} Sec. 1 Act relating to transplantation, hospital autopsis and the donation of bodies etc. 
\textsuperscript{107} Sec. 10 Transplant Act.
If the donor does not comprehend the information provided to her, the whole process of disclosure can be thought of as useless. An adequate transplantation law should hence explicitly require the donor to understand the information provided to her.108

1.2.3 Formal requirements

There is no consensus on the disclosure’s dependence on formal requirements.

A verbal dialogue between the potential donor and the person who informs her is necessary because it allows the potential donor to immediately ask questions. In addition, it is also a good idea for the given information to be presented to the donor in written form as well, which allows the donor a chance to re-read the information whenever she wants to.109 Such an approach is in accord with the Czech Republic,110 Germany,111 Hungary,112 the Netherlands,113 Poland,114 Spain115 and Switzerland,116 because those countries require the education of the potential donor to be in writing.

Quite a lot of countries considered who has to inform the donor. The countries that specify who the informant must be require him to be a physician. What kind of physician this has to be, and whether any kind of third person has to be present, is not regulated homogeneously. The attendance of a physician who is not part of the transplantation process should be required to ensure that the information is presented in an objective way.117 Nevertheless, the physician who actually performs the transplantation should be involved in the disclosure as well because she is familiar with the individual transplantation. The best practice regulation should therefore demand the presence of two physicians: the physician who performs the intended transplantation should inform the donor, and an additional physician who is not part of the transplantation process should be present as well.118

1.2.4 Disclosure of the recipient

As clarified above, the recipient always has to give valid consent, even if it is not explicitly stated in the national transplant law. Since the requirement of consent and the requirement of informing the person consenting are connected, a best practice regulation should require the recipient to be informed.

110 Art. 7 (2) Transplantation Act on Donation, Removal and Transplantation of Organs and Tissue and on the Amendment of some Acts.
111 Sec. 8 ÷ 4 Act on the Donation, Removal and Transplantation of Organs.
112 Sec. 209 (1) Act on Health.
113 Sec. 3, 2 Organ Donation Act.
116 Art. 9, 1 Transplantation Ordinance.
At the moment, only the transplant laws in Estonia, Hungary, Moldova, Poland, Portugal, Slovenia and Spain explicitly request for the recipient to be informed. The other transplant laws do not explicitly declare that the recipient has to be informed. Nevertheless, it can be assumed that many of the legal systems considered in this paper require the recipient to be informed before the transplant process takes place. This can be justified given the transplantation of an organ is a medical operation, which is usually considered to be justifiable battery due to the informed consent of the person solely concerned.

Because recipients usually only accept limited risks for the donor, his disclosure should contain information about his health, but also information about the donor's health and possible risks.

2 Suitability of the transplantation

The intended purpose of organ removal is to transplant the removed organ into the recipient to cure his organ failure. This purpose can be reached only if the transplantation is medically suitable. Consequently, living organ transplantation only makes sense in cases in which the recipient could be cured.

Thus, Bulgaria, the Czech Republic, Estonia, Lithuania and the United Kingdom require the donor and recipient to undergo a medical check-up prior to the process of organ transplantation.

In practice, the medical suitability of a transplantation can only be judged sufficiently after a medical evaluation. A best practice proposal should therefore require a medical check-up of donor and recipient prior to the LOD.

Since the purpose of organ transplantation is to cure the recipient, several laws explicitly require the expectation that the organ donation will benefit the recipient. This should apply to a best practice proposal as well.

In addition, a potential donor should be suitable to act as living organ donor. Furthermore, many experts recommend requiring a risk-benefit equation in the best practice proposal. Only a few national laws explicitly include a risk-benefit equation. In fact, only the

119 Sec. 6 (2) Transplantation of Organs and Tissues Act.
120 Sec. 209 (5) Act on Health.
121 Art. 16 (1) Law on the Transplant of Human Organs, Tissues and Cells.
123 Art. 7 Law on Harvesting and Transplanting Human Organs and Tissues.
124 Art. 6 I 2 The Removal and Transplantation of Human Body Parts for the Purpose of Medical Treatment Act.
125 Art. 6 Law Regulating Organ Recovery and Transplantation.
129 Art. 6 (1) Transplantation Act on Donation, Removal and Transplantation or Organs and Tissues and on the Amendment of some Acts.
130 Sec. 9 (1), 2) Transplantation of Organs and Tissues Act.
131 Art. 10, 8 Law on Donation and Transplantation of Human Tissues, Cells and Organs.
132 No. 59 Code of Practice 2.
Belgian, the Dutch, the Slovakian and the Slovenian laws define the risk-benefit equation. Furthermore, in Austria, a risk-benefit equation is common medical practice. Since LOD always involves one healthy person, the risks should be balanced against the potential benefits. In contrast, many doubt the risk-benefit ratio established by law is sufficient to justify the refusal of certain LOD's. They claim that it is untenable to prevent any LOD that is based on an informed, voluntary and well-considered wish. A best practice regulation should consequently contain the provision of a reasonable risk-benefit equation for the donor, but its requirements should not be too detailed or paternalistic. The decision should be made by the autonomous donor (and the recipient) and transplant team.

3 Minors and mentally incapacitated adults

All national laws treat minors and mentally incapacitated adults differently than competent adults. The intent of these particular requirements for minors and mentally incapacitated adults is to protect them because legal transactions typically do not only entail rights, but also duties. For example, Austria’s Sec. 21 (1) Civil Code states that minors are under the special protection of the law. The specific regulations for minors and mentally incapacitated adults are rather similar. The WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation states, “What is applicable to minors also applies to any legally incompetent person.” The majority of countries completely prohibits minors and mentally incapacitated adults from acting as living donors. A few countries, in contrast, allow them to donate an organ while alive if certain circumstances are fulfilled. The following chart shows the countries that allow minors and/or mentally incapacitated adults to act as a living organ donor in proportion to those that do not allow that (s. Figure 1).

Determining whether minors and mentally incapacitated adults should be completely prohibited from becoming a living organ donor, or whether they are allowed to do so under specific circumstances, is of great importance. LOD might have severe consequences for the donor. This also applies to the complete prohibition to become a donor, though.

3.1 Complete prohibition?

Many believe, specific rules for minors and mentally incapacitated adults must be established because they might not be able to evaluate the situation properly. Specific rules are perceived as a needed protection for them. This argument can either be used in favour of a complete prohibi-

134 Art. 6, Sec. 1 Law on Retrieval and Transplantation of Organs.
135 Sec. 3, 3 Organ Donation Act.
136 Sec. 36 (1) (c) Act on Healthcare, Healthcare-Related Services and on the Amendment and Supplementing of Certain Laws.
137 Art. 7 The Removal and Transplantation of Human Body Parts for the Purpose of Medical Treatment Act.
tion or in favour of allowing them to act as living organ donors under specific circumstances. A complete ban provides legal certainty and maximises the legal protection of minors and mentally incapacitated adults. Also, donations that occur within families, which describes the majority of LOD cases, can be very stressful for the donor, placing him under the pressure of his family. Hence, many assume that mature people are able to handle the pressure better than immature people, who depend on the family to a greater extent.

Opponents of a complete prohibition state that cases might exist in which LOD by a minor is ethically justifiable. They also criticise complete prohibition insofar as it does not take the differences between more or less mature minors into account. According to this view, the most suitable approach to regulate LOD of minors and mentally incapacitated adults is to assess the person’s capability individually. In England, the regulation for minors can serve as an example for this potential framework. There, the minor’s capability to consent is judged individually.

It is clear that minors and mentally incapacitated adults should receive more protection than competent adults. The most extensive protection would undeniably be to completely ban them from LOD. This, however, would most certainly lead to cases in which a prohibition would be ethically unjustified. 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.

3.2 Suggested requirements

Minors and mentally incapacitated adults should be allowed to donate a solid organ while alive if specific requirements are fulfilled. The requirements must be very strict, as the protection of minors and mentally incapacitated adults must be of the highest importance. The Joint Working Party of The British Transplantation Society and The Renal Association, for example, states that “[c]hildren should only be considered as living organ donors in exceptionally rare circumstances.”149 All requirements established must therefore be interpreted extremely narrowly. For any issue related to LOD in need of regulation that is not mentioned in the following, the requirements established for adults can be applied.

(1) The donor’s informed consent is absolutely essential. The person concerned must be competent to do so. Some mentally incapacitated adults may have the competency to consent. For minors, the capacity to give valid consent can often be answered affirmatively if the minor is older. If the surgeon is unsure of the minor’s or the mentally incapacitated adult’s capability to consent, he must refuse the LOD. In case a person is incapable of giving consent, this requirement cannot be fulfilled by a parent or a legal guardian. However, the parents of minors and the custodians of mentally incapacitated adults should be required to consent in addition to the potential donor’s consent.

(2) The potential donor and the intended recipient must have a close personal relationship. LOD by a minor most commonly occurs for the benefit of a sick sibling (or even a twin). It is often very difficult for a healthy minor to see his sibling suffering. An ill child has an influence on the whole family life. Furthermore, “transplants between siblings offer the best opportunity for a well matched graft […].”150 Whether other relationships are sufficient as well is doubtful. Since a parent’s death is a traumatic incident for a minor, it might make sense to allow a minor to donate to benefit a parent. He should, therefore, be allowed to donate to a sick parent if all other requirements have been fulfilled. Mentally incapacitated adults should also only be allowed to donate for the benefit of a sibling or a parent.

(3) The risks attached to the donations of different organs differ.151 Living kidney donation contains fewer risks for the living donor than the donation of other organs; it is the most common type of LOD. It consequently makes sense to only allow living kidney donation by minors and mentally incapacitated adults.

(4) Living kidney donation by a minor or a mentally incapacitated adult should be the ultima ratio. This should be made clear by law. The Swedish regulation can serve as an example. It only allows LOD by a minor if “medically suitable biological material cannot be taken from anybody else.” This means a minor is only permitted to donate if there is no other donor who matches genetically or is equally suitable.

(5) An independent commission should have to approve the intended LOD by a minor or a mentally incapacitated adult.

We can assume that a best practice regulation would not absolutely prohibit minors and mentally incapacitated adults from becoming organ donors. It would rather contain specific requirements that only allow them to act as living organ donors in very exceptional cases. Sweden can again serve as a model, because no donation of a solid organ by a minor has been approved yet, even though the possibility is granted by law.152 This indicates that the mere legal possibility of LOD by minors and mentally incapable adults does not always result in the actual realisation of it. This must be kept in mind for the best practice proposal as well.

150 Ibid., p. 157.
152 Information from A. Lennerling; information from C. Möller.
4 Restrictions on living organ donation by competent adults

Should the donor-recipient relationship in LOD be restricted by law?
(1) We analyse whether a restricted or an unrestricted donor-recipient relationship is preferable.
(2) We offer suggestions for how to deal with the different types of LOD.153

4.1 Debate on restriction of donor-recipient relationship required for living organ donation

The national transplant laws considered do not have a common standard regarding the required donor-recipient relationship. This aspect is noteworthy, since regulations that confine the range of possible living organ donors or even prohibit certain persons from becoming living donors for particular recipients affect the total amount of LODs and even impede medically possible LODs in individual cases.154

Whether a certain relationship between donor and recipient is required, and what constitutes this relationship, is answered differently. The debate about the restriction of the donor-recipient relationship basically revolves around the following two questions:
(1) Is a genetic relationship necessary or is an emotional relationship sufficient?
(2) Should no relationship at all be demanded?

A prominent debate is whether LOD should only be allowed in a genetic relationship. This means that a mere emotional relationship (e.g., partner, close friend)155 between a potential donor and a potential recipient is insufficient. In the past, immunological reasons were brought forward as an argument for only permitting LOD between genetically related persons. These reasons have been recently contradicted by the fact that there is no medical difference anymore between the results of LODs of genetic relatives and non-genetic-relatives.156 That organs with low tissue compatibility can lead to very good outcomes is essentially the result of the invention of new pharmaceuticals. The differences of the functionality between organs donated by genetically related persons or by those with low tissue compatibility shrink increasingly.157 This particularly applies to kidney donation, which is the most important type of organ donation in terms of its being the most often donated organ.158

The discussion in Germany will be used as an example. The German Bundestag argues that a restriction of the donor-recipient relationship guarantees the voluntariness of the LOD and that a general liberalisation of the circle of donors entails the danger of organ trade.159 Several academics disagree with the aspect that a relationship guarantees the voluntariness of LOD. They state that

153 See chapter 4 for the explanation of the different types of LOD.
the donor might be pressurised within the family as well.\textsuperscript{160} They assert that family members might express a certain expectation towards the potential donor or his family status might be affected seriously if he refuses to donate. As a consequence, it is considered to be very difficult for the potential donor to disengage himself from this family pressure.\textsuperscript{161} Other arguments against the German Bundestag claim the voluntariness and the absence of financial incentives can be assured for all types of LOD, for example, the donation or allocation of the organs by a central authority, such as Eurotransplant, could be anonymous, making the mentioned risks non-existent.\textsuperscript{162} In addition, prosecuting organ trade as a criminal offence is generally mentioned as a safeguard to assure that the potential costs of organ trade outweigh the benefits.\textsuperscript{163}

One argument by the German Federal Constitutional Court is similar to the German Bundestag’s argument. According to the court, which is usually not very paternalistic,\textsuperscript{164} they must ensure that people are protected from significantly harming themselves personally.\textsuperscript{165} This has often been criticised and is countered with the arguments that, first, protecting people from harming themselves is not legitimate and, second, paternalism by law is problematic in this case since a prohibition to donate not only affects the potential donor, but also another person, namely the organ recipient.\textsuperscript{166}

Many argue that people have different motives for donating an organ while being alive. A complete ban of unspecified LOD would lead to the nullification of several good intentions.\textsuperscript{167} Opponents are sceptical particularly with regard to donations for unknown recipients.\textsuperscript{168} The proponents of an unrestricted donor-recipient relationship, in contrast, claim that empirical evidence shows that people who donate organs to unspecified recipients are “very self-directed and without psychopathology.” Accordingly, mistrust only arises because the majority does not aspire to those altruistic principles themselves.\textsuperscript{169}

Those opposed to the requirement of a specific relationship between donor and recipient bring out that the original relationship between donor and recipient might change after the transplantation.\textsuperscript{170} Even though the donation might have had altruistic motives, the recipient will usually feel obligated to show gratitude towards the donor. This feeling can even be so strong that the intended recipient rejects the LOD offered by an emotional or genetic relative. With respect to the recipient’s gratitude, it is possible for the donor to be disappointed if the recipient is not as thankful as expected.\textsuperscript{171} With regard to life partners, the partnership could even end, which might lead to the donor regretting his donation. A failed transplantation could also have negative consequences for the relationship. In addition, the organ recipient might feel pressured after the transplantation, particularly if the donor watches how he ‘treats’ the donated organ.\textsuperscript{172} The opponents of the restriction


\textsuperscript{163} Schroth, in Gutmann et al. (ed.) (2003), p. 138 f.


\textsuperscript{166} Gutmann, Vol. 52 Neue Juristische Wochenschrift 3387, 3388 (1999).


\textsuperscript{169} Price (2010), p. 214.

\textsuperscript{170} Cf. Schutzeichel (2002), p. 188 ff.

\textsuperscript{171} Ibid.

\textsuperscript{172} Ibid.
of the donor-recipient relationship argue that all these aspects of pressure or any sense of obligation are not possible with regard to LOD if the recipient is unknown.\textsuperscript{173}

This approximate presentation of the debate on a possible donor-recipient relationship makes clear that several arguments exist for each position. This explains why the countries approach the aspect in several different ways.

4.2 National regulations

None of the considered countries restricts LOD to those who are genetically related anymore. Several countries restrict LOD to relatives – genetic and emotional. Within this group of countries, the regulations are still fairly different, because some countries list the allowed donor-recipient relationships exhaustively, while others, in contrast, contain a list of allowed relationships, but additionally include an open clause that makes an extension of the explicitly stated relationships possible. In contrast, a considerable amount of countries do not restrict the donor-recipient relationship at all. Thus, on principle, those countries allow a LOD for any recipient. However, different procedural safeguards have been established.

Following our presentation of the different restrictions regarding the donor-recipient relationship, we explain the ‘special cases’ associated with the circle of possible donors.

The following chart presents the proportions of the different regulations of the required donor-recipient relationship.

4.3 Best Practice Regulation

(1) We use the conclusions drawn in chapter 4, which considered the main arguments about the necessity and legitimacy of legal restrictions of the donor-recipient relationship, to establish a best practice proposal for this common concern.

(2) Afterwards, we examine the extent of the fundamental rights established in the CFREU, and how they can be interpreted in light of the donor-recipient relationship.

Finally, we draw our own conclusions on whether the donor-recipient relationship should be restricted or not.

### 4.3.1 Results of chapter 4

In favour of restricting the donor-recipient relationship, many argue that LOD could be viewed as a violation of the principle of nonmaleficence;\(^{174}\) it contains risks for the donor. The principle of autonomy is used as a counterargument. This principle implies that every person has a right of self-determination,\(^{175}\) which includes the right to decide about one’s own body.\(^{176}\) Because the risks are equally high for all types of LOD, citing them cannot serve as a valid reason to restrict LOD to direct LOD.\(^{177}\) In favour of restricting the donor-recipient relationship, some authors claim that unrelated donors do not benefit as much from LOD as related donors,\(^{178}\) and that the special relationship between donor and recipient exclusively justifies LOD.\(^{179}\) Both statements may be true, but neither is convincing enough to prohibit unspecified LOD. The most relevant feature of any LOD must be the donor’s concern for the needs of others. This applies to any (non-commercial) LOD, regardless of the relationship between the donor and the recipient.\(^{180}\)

The second relevant aspect of the donor-recipient relationship is safeguarding the donor’s voluntariness. Many believe that unspecified LOD is connected to involuntariness. The German Bundestag, for example, claims that only familial relationships or other close relationships guarantee voluntariness in LOD.\(^{181}\) Social research, in contrast, demonstrates that organ donors with a competent, informed and voluntary decision to act altruistically towards strangers can be found in great numbers.\(^{182}\) Involuntary decisions could occur in any type of LOD,\(^{183}\) while every type of LOD also contains cases that are the result of a voluntary decision. The best approach, therefore, is to judge each case individually and to avoid the view that only certain donor-recipient relationships should be allowed.\(^{184}\)

Third, some believe that the general legalisation of LOD would increase the pressure on living individuals to become organ donors. This belief has led many to demand that the donor-recipient

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\(^{180}\) Hilhorst et al., Vol. 24 Transplant International 1164, 1167 (2011).

\(^{181}\) Bundestag printed paper 13/4355 (1996), p. 20; see also German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 3b.


relationship should be restricted.\textsuperscript{185} These reservations can be easily dispelled: giving people the chance to choose to help, or even save a person, cannot be equated with imposing a duty on people to actually become an unspecified living organ donor.

Fourth, unspecified LOD\textsuperscript{186} and cross-over LOD\textsuperscript{187} are associated with organ trade. The possibility that unspecified LOD might cause commercialisation and organ trade can be nipped in the bud, though, if the donation occurs within a pool of organs that is handled by a neutral agency which coordinates the organ transplantation, organ allocation and maintains the anonymity of the donor.\textsuperscript{188} Furthermore, past experiences of LOD between persons who were not closely related to each other demonstrate that no uncontrollable danger of commercialisation exists.\textsuperscript{189} The concern with respect to cross-over LOD is dispelled by referencing the donor’s motives: to help a relative.\textsuperscript{190}

None of the arguments provided in favour of a restriction of the donor-recipient relationship seems tenable. There is no class of donors and no kind of donor-recipient relationship that should be generally dismissed by law.

\subsection*{4.3.2 Charter of Fundamental Rights of the European Union}

Potential donors who are not included in the allowed circle of donors in a concrete case cannot donate. This restriction is thus essentially a complete prohibition for them. Hence, if a complete prohibition of LOD is in conflict with the \textit{CFREU}, then a restriction of the donor-recipient relationship is also in conflict with the \textit{CFREU}.

A complete prohibition of LOD might conflict with Art. 2 (1), Art. 3 (1) and Art. 35 CFREU. In addition, the donor’s right of self-determination must be kept in mind.

The \textit{CFREU} protects the right to life\textsuperscript{191} and the person’s right to integrity.\textsuperscript{192} The fundamental right declared in Art. 2 (1) is infringed upon if an addressee of this regulation causes a person’s death.\textsuperscript{193} Completely prohibiting LOD would deprive several sick patients of this option and would consequently likely cause the death of (some of) those. Restricting LOD to specific donor-recipient relationships would make certain LODs impossible, consequently causing many potential recipients to die (unnecessarily). An impairment of Art. 3 (1) \textit{CFREU} exists if a person, who is engaged in fundamental rights, intervenes on a person’s physical integrity in a positive way.\textsuperscript{194} Completely prohibiting LOD would be disadvantageous for the potential recipient’s physical integrity and could be considered as being in conflict with Art. 3 (1) \textit{CFREU}. If certain LODs are prohibited, because they lack a sufficient donor-recipient relationship, the results are the same. In general, with regard to Art. 2 (1) and Art. 3 (1) of the \textit{CFREU}, the same principle can be derived from what the German Constitutional Court decided regarding LOD, a decision based on the basic right in the German Constitution: “Whenever legal regulations entail that a citizen in need of treatment is denied a therapy which, according to the state of medical research, could be provided to him or her, and

\begin{thebibliography}{99}
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\item[186] Cf. Evans, Vol. 15 Journal of Medical Ethics 17, 18, (1989); German Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, at 3b.
\item[187] Bundestag printed paper 15/5050 (2005), p. 42, 73 f.
\item[191] Art. 2 (1) CFREU.
\item[192] Ibid., Art. 3 (1).
\item[194] Jarass (ed.) (2010), Art. 3 at 7.
\end{thebibliography}
which would entail a prolonging of life or at least a substantial mitigation of the ailment, the constitutionally guaranteed basic negative right to life and health is infringed upon.\textsuperscript{195}

Art. 35 \textit{CFREU} demands a high level of human health protection. It does not demand the highest level of human health protection,\textsuperscript{196} but withholding medically possible (and normatively justifiable) treatment from sick people does not ensure a high level of human health protection.

The \textit{CFREU} also protects the right of self-determination about one’s own body.\textsuperscript{197} A complete prohibition of LOD would be in conflict with this fundamental right; restricting the donor-recipient relationship would be in conflict as well.

A regulation that only allows certain people to become living organ donors might also contravene the principle of equal treatment established in Art. 20 \textit{CFREU}. An interference with Art. 20 exists if comparable situations are treated unequally.\textsuperscript{198} Several national transplant laws regulate that relatives are allowed to act as living organ donors, while people who intend to donate an organ to a stranger are not. Can both types of LOD be compared? We concluded in chapter 4 that the arguments in favour of a distinction between direct LOD and unspecified LOD do not bear close scrutiny. One can therefore assume that a different treatment would interfere with Art. 20 \textit{CFREU}.

To sum up, a complete prohibition of LOD would be in conflict with the \textit{CFREU}. Restricting the donor-recipient relationship has an equal effect on willing donors that are outside of the allowed relationships. General restrictions on the donor-recipient relationship are, hence, also in conflict with the \textit{CFREU}.

\subsection*{4.3.3 Interim result}

Chapter 4 and the \textit{CFREU} both argue against a restriction of the donor-recipient relationship for LOD. It seems preferable to evaluate concrete risks, rather than to distinguish between relationships.\textsuperscript{199} As a consequence, a best practice regulation should not contain a restriction of the donor-recipient relationship, but should require case-by-case decisions.\textsuperscript{200}

\section*{4.4 Special cases}

Several types of LOD are medically possible.\textsuperscript{201} The main argument in favour of allowing many types of LOD is that they are often able to overcome any incompatibility between the willing donor and the intended recipient, making it possible to increase the amount of donor organs. Critics fear the potential donor might be inflicted with increasing pressure. Overall, we concluded that cross-over LOD, living paired cascade exchange, unspecified LOD and pool donation seem to be legitimate. Unbalanced living paired exchanged, directed altruistic LOD, unspecified non-directed donation catalysing cascade exchanges and list-paired exchanges, in contrast, seem to be rather problematic, although there is hardly a reason for legally banning them.

A best practice regulation cannot mention every type of LOD. This would cause an impracticable extension of the law. Also, since the medical possibilities are steadily increasing, the law

\begin{footnotesize}
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\item \textsuperscript{195} Federal Constitutional Court, August 11, 1999, Case No. 1 BvR 218/98, in Vol. 46 Neue Juristische Wochenschrift 3399, 3400 (1999).
\item \textsuperscript{196} Nußberger, in Tettinger/Stern (ed.) (2006), Art. 35 at 50.
\item \textsuperscript{197} Borowsky, in Meyer (ed.) (2011), Art. 2 at 35.
\item \textsuperscript{198} Hölscheidt, in Meyer (ed.) (2011), Art. 20 at 15; Jarass (ed.) (2010), Art. 20 at 7.
\item \textsuperscript{201} Chapter 4.
\end{itemize}
\end{footnotesize}
would be obsolete very quickly and, thus, would need to be revised continuously. A best practice regulation should, therefore, not determine which types of LOD are to be permitted or prohibited. Rather, one should be able to interpret the best practice proposal’s particular regulations in light of the different types of LOD, and then judge whether or not the LOD is legitimate. This approach is in the style of the *Principles of European Contract Law*. Those rules are also intended to be very flexible, making it possible to consider future developments in the legal thinking of contract law. The Principles do not regulate every eventuality, because that would be too detailed and concrete and would constrict the further development of European contract law.202

Most types of LOD can only exist if a sufficient national scheme has been established. Whether the countries or national transplantation systems do so is up to them, although there are good reasons for such policies. The Netherlands203 and the United Kingdom204 have, e.g., established such a scheme for cross-over LOD.

5 Subsidiarity205

There is no consensus between the countries about the relationship between (1) LOD and post-mortem organ donation and (2) LOD and alternative therapies.

5.1 Relationship between living organ donation and post-mortem organ donation

There is no consensus between the countries on whether LOD should be subsidiary to post-mortem organ donation or not. The laws in the Czech Republic,206 Estonia,207 Finland,208 Germany,209 Greece,210 Hungary,211 Lithuania,212 Moldova,213 Portugal214 and Slovakia215 contain a provision which prohibits the performance of LOD when an organ from a deceased person is available. In contrast, Bulgaria, England, Italy, Latvia, the Netherlands, Norway, Poland, Scotland, Slovenia, Spain, Sweden and Switzerland do not explicitly state that post-mortem donation and LOD are ranked equally. These countries do not regulate the relationship between LOD and post-mortem donation at all. We can conclude that these two types of organ donation are equal.

205 The aspects connected to the issue of subsidiarity have already been described in chapter 4.
206 Art. 3 (1) b) Transplantation Act on Donation, Removal and Transplantation of Organs and Tissue and on the Amendment of some Acts.
207 Sec. 9 (1) 4) Transplantation of Organs and Tissues Act.
208 Sec. 2 II Act on the Medical Use of Human Organs and Tissues.
209 Sec. 8, 1, 1, No. 3 Act on the Donation, Removal and Transplantation of Organs.
211 Sec. 203 (1) Act on Health.
212 Article 10, 1.Law on Donation and Transplantation of Human Tissues, Cells and Organs.
213 Article 15, (1) Law on the Transplant of Human Organs, Tissues and Cells.
214 Art. 6, 2 Law on Harvesting and Transplanting Human Organs and Tissues.
215 Sec. 36 (1) (d) Act on Healthcare, Healthcare-Related Services and on the Amendment and Supplementing of Certain Laws.
Most argue that LOD should be subsidiary because they believe this is the only way to ensure the protection of potential living organ donors, since LOD requires a healthy person to become part of a surgery that contains risk.\(^{216}\) This is sometimes considered as a violation of the principle of nonmaleficence.\(^{217}\)

In contrast, one strong argument against the principle of subsidiarity is that the donor has a right of self-determination.\(^{218}\) This even applies to self-harming behaviour.\(^{219}\) The potential organ recipient has a right of self-determination as well. So, if she has a choice between receiving a LOD or a post-mortem organ donation, she should be able to choose which organ she wants to receive.\(^{220}\) Living kidney donation leads to better short-term and long-term results than post-mortem kidney donation.\(^{221}\) 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.\(^{222}\) Another convincing argument against the principle of subsidiarity is that 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.\(^{223}\)

When weighing the conflicting arguments, the right of self-determination that results from the principle of autonomy must be rated rather highly. This right is protected by the CFREU, which confirms that all countries of the European Union consider this a fundamental right. Although this right is not absolute, the arguments mentioned in favour of the principle of subsidiarity are still not convincing. Potential living organ donors should without doubt be protected, but this is also possible without restricting their right of self-determination; for example, safety by procedure\(^{224}\) would be a less drastic and therefore preferable action.

In a best practice proposal, LOD should not be subsidiary to post-mortem donation.\(^{225}\) Nevertheless, post-mortem organ donation should never be regarded as secondary to LOD, as it is a very valuable means to alleviate the organ shortage.\(^{226}\)


\(^{225}\) Gutmann/Schroth (2002), p. 82; Gutmann (2006), p. 84.

5.2 Relationship between living organ donation and alternative therapies

Several laws contain a provision stating that performing LOD is only legitimate when other methods of therapy are less effective or do not provide comparable efficiency. The laws of Bulgaria,227 the Czech Republic,228 Finland,229 Greece,230 Lithuania,231 Moldova,232 Slovakia,233 Slovenia234 and Switzerland235 contain a provision stating that LOD is only legitimate when other methods of therapy are less effective or do not provide comparable efficiency. These national laws only regulate LOD insofar as it is illegal in cases where an equally effective alternative therapy exists. No further details are provided.

In contrast, the rule of subsidiarity in the Netherlands is only applicable under certain circumstances. The regulation in the Netherlands states, “If it is reasonable to assume that the removal of the organ during the donor’s life will have permanent consequences for the donor’s health, the organ shall be removed only if the life of the recipient-to-be is at risk and if no other equally suitable treatment option exists.”236 This regulation leads to the assumption that LOD is ultimum refugium in the Netherlands. However, in the medical practice that is not the case.237

In contrast, Belgium, England, Estonia, Germany, Hungary, Italy, Latvia, Norway, Poland, Portugal, Scotland, Spain and Sweden do not have any regulation regarding the relation of LOD to alternative therapies. Consequently, it is assumed that the two types of treatment are equal.

Art. 12 d Swiss Transplantation Act states, “Organs, tissues and cells may be removed from a living person if: […] the recipient cannot be treated with any other therapeutic method with comparable benefit.” This regulation clarifies that LOD is the ultima ratio, but does not cause a patient suffering from kidney failure to depend on the worse option of dialysis if LOD is possible.238 Hence, a regulation like the one in Switzerland is recommendable.

6 Procedural issues

As this best practice proposal suggests eliminating legal restrictions on the donor-recipient relationship, it seems important to establish procedural safeguards in addition to the material aspects just presented ("Safety by procedure"239). In liberal societies, people generally are allowed to behave unwisely, to harm or cause disadvantages to themselves without the law protecting them by stipulating a certain procedure. However, it may be specific to LOD that it does not only concern the potential donor, but also the surgeon and the transplantation team. This distinguishes LOD from

227 Art. 4. (2) Law of the Transplantation of Organs, Tissues and Cells states that “[t]ransplantation shall be carried out only when other methods of therapy are less effective or not applicable”, thus, refers to transplantation in general, what also includes LOD.
228 Art. 3 (1) b) The Transplantation Act on Donation, Removal and Transplantation of Organs and Tissues and on the Amendment of some Acts.
229 Sec. 2 II Act on the Medical Use of Human Organs and Tissues.
231 Article 10, 1. Law on Donation and Transplantation of Human Tissues, Cells and Organs.
232 Article 3, (b) (general) and Article 16, (1) (only for LOD) Law on the Transplant of Human Organs, Tissues and Cells.
233 Sec. 36 (1) (e) Act on Healthcare, Healthcare-Related Services and on the Amendment and Supplementing of Certain Laws.
234 Art. 2 II The Removal and Transplantation of Human Body Parts for the Purpose of Medical Treatment Act.
235 Art. 12, d. Federal Act on the transplantation of organs, tissues and cells.
236 Sec. 3, 3 Organ Donation Act.
237 Information from M. Bos.
self-harming behaviour that only concerns the acting person and gives rise to the idea of procedural safeguards, especially to ensure the autonomy of the donors’ decisions. We will therefore proceed by examining what procedural regulations should be part of a best practice regulation.

6.1 Commission for living organ transplantation

(1) We describe certain national regulations before
(2) suggesting a regulation for a best practice proposal.

6.1.1 National regulations

Most countries have established some kind of independent authority as a safeguard for LOD. Both the type of the commission and its composition differ, though.

First, the donor’s consent and autonomy play a major role in LOD. Adequate procedures are necessary to ensure the donor acts voluntarily. According to some experts, hospitals should “institutionalize a careful and comprehensible screening procedure” to evaluate the donor’s motivation. The regulation in the German Act on the Donation, Removal and Transplantation of Organs could serve as a model for an adequate screening procedure (although Germany, having severe limitations concerning the classes of living donors, does not consistently rely on a safety-by-procedure-system). According to the said act, a commission consisting of a physician, a lawyer and a psychologist must investigate and confirm that there is no substantiated reason to assume that the donor’s consent is not being given freely and that the organ is not the object of prohibited organ trade. The commission’s decisions are not binding for the surgeon but still have a considerable impact. A best practice regulation should clarify whether decisions by the commission in charge are binding or mere suggestions. In favour of making decisions binding, some assert that the regulation is a safeguard for the donors. In contrast, it might interfere with the donor’s right to self-determination or with the recipient’s fundamental right to life and health. Additionally, some question if the surgeon should (or can) be released from having the final responsibility to decide whether the LOD will be executed or denied. Nevertheless, because of the great importance of voluntariness, the commission’s decisions should be binding. The disadvantages such a provision might have should be considered in light of the commission’s composition and the decision-making process. Apart from the aspects just mentioned, the acting of the commission can be classified as weak paternalism. Even if the commission’s decisions were not binding, they would still have

244 Sec. 8 III 2 Act on the Donation, Removal and Transplantation of Organs.
245 Ibid.
relevance for the realisation of donors’ and recipients’ fundamental rights. This, however, is not considered problematic as long as the commission’s decision is based on the aspect of voluntariness and interprets this in an appropriate way.\textsuperscript{254} The details of the German Commissions’ decision-making criteria, which are stipulated in regulations from 16 different Länder-legislation, however, are far from being well-defined. This causes arbitrariness and uncertainty. A best practice regulation should not adopt this approach.\textsuperscript{255} Rather, even federalist countries should provide a regulation that applies to the whole country uniformly.\textsuperscript{256}

Seeking a uniform procedure, it seems useful to require the approval of an independent commission for every LOD. This is usually required in countries that do not consider informed consent as sufficient to justify LOD. The British Human Tissue Authority may provide guidance here. It was established “to oversee and control the working of the [Human Tissue] Act.”\textsuperscript{257} The United Kingdom does not restrict the donor-recipient relationship, but every LOD needs to be approved by the Human Tissue Authority through an independent assessment process.\textsuperscript{258} The Human Tissue Authority is a state authority with a wide range of people from different professions. It turns down offers of inappropriate LODs. It is suggested that this model works well.\textsuperscript{259} Only a few rejections have taken place; numerically eight applications to perform a LOD have been turned down since 2006.\textsuperscript{260} Clinicians as well as most patients like the approach, inter alia, because it is very flexible and considers each case individually.\textsuperscript{261}

Third, a few countries demand every LOD to be disclosed. This makes the collection of data of LOD and the traceability of all organs donated by living persons possible. The duty to disclose every LOD to a central commission should therefore be written down in a best practice regulation.\textsuperscript{262} This could be modelled on the Bulgarian regulation. The Bulgarian Law of the Transplantation of Organs, Tissues and Cells stipulates that each medical establishment that removes organs from living donors has to inform the Executive Agency for Transplantation thereof at least seven days in advance.\textsuperscript{263} After the organ removal, the medical establishment has to register the procedure within seven days with the Executive Agency for Transplantation.\textsuperscript{264} This makes the tracking of LOD less difficult.

### 6.1.2 Suggestion for a best practice proposal

The procedural approach that should be preferred in a best practice proposal is still undecided, especially with respect to establishing a commission for LOD.

(1) Not all countries stipulate certain procedures by law at all. Denmark, Latvia, the Netherlands and Switzerland, for example, neither restrict the donor-recipient relationship nor require any particular procedures. Countries with no established legal procedures for LOD often establish procedures at the hospitals or transplant centres themselves. The Netherlands, Switzerland and the USA can serve as examples, among others. None of these countries stipulates any proce-
dures or commissions by law. In the Netherlands and Switzerland, the hospital/transplant centre responsible for the donor evaluates him carefully and follows certain guidelines. The guidelines are not prescribed by law, but are made by the hospitals/transplant centres themselves. They are generally based on their own research and take into account international consensus documents like the Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor (2004) or the Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor (2006). In the USA, Congress passed the National Organ Transplant Act in 1984. It does not contain rules about procedures, but the hospitals nevertheless work according to specific procedures and professional standards. The Organ Procurement and Transplantation Network (OPTN) that has been created under the National Organ Transplant Act established several guidelines, for example, Guidance for the Medical Evaluation of Potential Living Liver Donors and Guidance for the Informed Consent of Living Donors. In addition, the OPTN/UNOS Living Donor Committee is involved in each case. It “considers issues relating to the donation and transplantation of organs from living donors to recipients. The committee makes recommendations to improve the process of living donation and transplantation.” Such guidelines are generally more flexible than legal rules, and they allow for innovation as a result of pluralistic approaches, because the guidelines are easily adapted to changing situations. One negative aspect of this approach is that not one consistent procedure exists nationwide. This might cause legal uncertainty and unequal treatment of patients or make it difficult to supervise the hospital's compliance to those instructions and professional standards or even to sanction non-compliance. To sum up, this approach is good and seems sufficient for countries with hospitals that are highly developed and take an active part in the ethical and legal discussions about LOD. In these cases, legal rules on LOD procedures might be superfluous.

(2) Another idea would be to stipulate the legal rules for decentralized procedures that take place at hospitals. Thus, legal rules would exist, but would not call for a state commission. This approach might only make sense for general provisions which are open for individual development. It might be possible to combine the advantages of legal rules with the advantages of hospital established procedures. A minimal version of this model can be found in Switzerland. Art. 10 Transplantation Ordinance (not the Swiss Federal Act on the Transplantation of Organs, Tissues and Cells itself) stipulates that an independent person, one who is experienced with LOD, must ensure that the LOD is voluntary and free of charge. The person in charge has to keep records of his meeting with the potential donor, and he must keep this record separate from the patient's records. If the potential donor is rejected, he may obtain a second opinion.

(3) A further approach would be a system of multiple state-run commissions or commissions defined by public law, respectively, based on a common legal basis. Germany, being the main example, established incomplete rules with respect to decentralized commissions. Only parts of the procedures are regulated by federal law. This causes legal uncertainty because the details of the working methods of the commission differ in the federal states. To stipulate procedures by law incompletely is inconsistent. This approach is therefore not worth following. In Germany,
the federal lawmaker himself should establish the essential rules for how the commission should proceed, he should lay down that donor and recipient have to be heard personally by the commission and he should determine the composition of the commission. In addition, the commission should follow a standardised approach with respect to procedures, but also to material decision criteria.\textsuperscript{272}

(4) The United Kingdom, in contrast, created a central state commission by law, the Human Tissue Authority. Having a central state commission is positive insofar as it ensures that the same working methods and criteria are applied nationwide, guaranteeing legal certainty and equal treatment of comparable cases. This also makes supervision possible.

The functions of the regulations in the United Kingdom and Germany are comparable after all, but the approach in the United Kingdom is more consistent. It creates complete procedures by law that are uniform nationwide. The countries that choose to establish procedures by law should hence follow the model of the United Kingdom. Also, when again considering the donor-recipient relationship, the United Kingdom is more flexible than Germany. The law as such does not make any general restrictions, but every LOD is evaluated by the Human Tissue Authority. The German regulation, in contrast, restricts LOD from the beginning on and involves a commission in addition.\textsuperscript{273} The United Kingdom, consequently, is better suited to cope with the recommendation to provide “safety by procedure.”\textsuperscript{274}

All in all, it can be seen as advantageous for a hospital to create its own procedures, but a central regulation has advantages as well. Since the countries are very different, it is impossible to determine one regulation to be best for all countries considered. It can be concluded, though, that a commission should consist of independent\textsuperscript{275} experts from different professions to examine and ensure the voluntariness of the donor (and the recipient). It should apply consistent criteria and apply them in an equal manner. A commission must usually authorise each LOD individually in countries that do not regard a donor’s consent as sufficient to justify LOD.

### 6.2 Transplanting person and location of transplantation

It is an agreed upon standard that a physician has to carry out the organ removal and the transplantation, but further requirements differ. In addition, several laws in the countries considered contain rules about the permissible locations. LOD contains a surgery. That it needs to be carried out by a physician in an appropriate hospital or transplantation centre is self-evident.\textsuperscript{276} A best practice regulation does not need to include that requirement explicitly.

### 6.3 Post-care

Only a few national laws mandatorily require care to be continued after the transplantation. In Austria,\textsuperscript{277} Germany\textsuperscript{278} and the Netherlands,\textsuperscript{279} donor and recipient are included in a post-care

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\textsuperscript{272} Gutmann (2011), p. 6 ff.
\textsuperscript{273} Ibid., p. 3.
\textsuperscript{277} Sec. 8 III 1 Act on the Donation, Removal and Transplantation of Organs.
\textsuperscript{278} Information from M. Bos.
process. In contrast, Bulgaria, the Czech Republic, Portugal and Spain only concentrate on one of the patients.

The main aim of post-care is to guarantee ideal medical and psychological care for the donor and recipient, ensuring the success of the transplantation in the long run. Appropriate post-care for donor and recipient should be stipulated by any adequate transplantation law. This is in accordance with the Directive 2010/45/EU on Standards on Quality and Safety of Human Organs intended for Transplantation. It requests that “[m]ember states shall endeavour to carry out the follow-up of living donors [...].” The current change in Dutch legislation may serve as a model for this requirement. It encourages living organ donors to undergo regular check-ups after the donation. The Ministerial Decree on Basic Health Insurance, which came into force on 1 January, 2012, declares that the arising expenses will be reimbursed by the basic health insurance. Bos, a member of the Health Council of the Netherlands, explained that the purpose of this decree is “to make the cost of yearly follow-up health check-up of living donors exempt from the mandatory own risk deductible (leading to loss of no-claim). This means that for living donors the cost of the yearly health check-ups is not considered as being part of the own risk deductible (every insured Dutch citizen has to pay the first Euro 220,– of their health care cost from their own pocket). This measure was taken to avoid that healthy living donors who have no other health care costs, would skip their yearly check-up because it would cost them money.

6.4 Donor registry

That donors are rarely registered in a centralised database is unacceptable. The key justification of LOD is the donor’s informed consent. Legitimate interest in the facts for a medical disclosure makes it necessary to establish a registry that records perioperative complications and impairments. It is, in addition, an effective instrument to ensure a constant post-care of the donor.

The Swiss Organ Living Donor Health Registry might serve as a model. It was established in 1993 and was the first living donor registry worldwide. One aim of the registry is to include and analyse post-LOD complications and problems in the long term and on a regularly basis. In addition, the registry should ensure that post-care is executed by the physician and that the donor’s medical care for the LOD is not neglected. The registry is also intended to provide a fast reaction

280 Art. 34 Law of the Transplantation of Organs, Tissues and Cells.
281 Art. 6 (4) Art. 6 (5) Transplantation Act on Donation, Removal and Transplantation or Organs and Tissues and on the Amendment of some Acts.
282 Art. 9, 1 Law on Harvesting and Transplanting Human Organs and Tissues.
283 Art. 9, 7 Royal Decree 2070/1999.
287 Information from M. Bos.
to any adverse effects. Art. 16 e Transplantation Ordinance contains details on how to ensure quality and the donor’s post-transplant follow-up. According to the Ordinance, medical and psychological data must be collected prior to the surgery and afterwards with the donor’s consent. The donor must be offered the chance to receive lifelong check-ups. The results of his check-ups should be evaluated on a regular basis and made available to all transplant centres. The donor must also be informed of the results of his check-up and should be advised if any additional measures are necessary. The results relevant for health will be incorporated in the disclosure of future donors.

A best practice regulation should demand that “[m]andatory organ-specific registries of transplant recipients and donors should be assembled to enable annual review of data.” The constant collection of data must be obligatory, and a legal foundation is necessary. When establishing a donor registry, (national) data protection regulations must be complied with.

7 Social security regulations for donors

With respect to the social security regulations for donors, no consensus exists. LOD is very expensive and might cause financial or economic disadvantages for the donor. The aim should be to protect her in the best possible way; she should be completely carefree. This should be regulated by law. The following will concentrate on (1) the insurance for the donor and (2) her reimbursement.

7.1 National regulations

In Belgium, Bulgaria, Hungary and Latvia, a state-owned or state-controlled institution pays the incurred expenses. However, the acting state institution and the expenses it covers vary. Since LOD is for the benefit of the organ recipient, in the Czech Republic, Estonia, Germany and Switzerland, the recipient’s insurance company pays the donor’s costs.

295 Bundestag printed paper 15/5050, p. 54 f.
298 Ibid.
304 Art. 4, Sec. 2 Law on Retrieval and Transplantation of Organs.
305 Art. 16 Law of the Transplantation of Organs, Tissues and Cells.
306 Sec. 207 (2) Act on Health.
308 Sec. 35 a Law on the Public Health Insurance.
309 Sec. 14 & 15 Transplantation of Organs and Tissues Act.
312 As an argument in favour of this, it is stated that LOD saves money for the recipient’s health insurance. First, LOD saves about 180,000 Euros in ten years in comparison to dialysis (Teubner (2006), p. 4; cf. calculation based on Landtag of Bavaria printed papers 14/1450, p. 3). Second, the recipient can resume working after living organ
A few countries do not hold the state institution or the recipient’s insurance company liable to pay the expenses.

In **Austria**, all costs that are connected to the organ removal and the preparation are covered by the donor’s health insurance, despite the fact that the donor is healthy and his life does not depend on LOD. In the occurrence of an event that is insured, the organ donation can be equated with an illness pursuant to Sec. 120 a **General Social Insurance Law**. In **Portugal**, the donor has the right to medical assistance until he is fully recovered. He is also fully compensated for the damage suffered. Insurance is mandatory for the donor to be supported by the transplanting establishments.

In **Moldova**, not one single institution is responsible for paying the costs of the transplantation. Actually, those costs may be covered by (1) the National Health Insurance Company, (2) the state budget, (3) payments/fees for medical services that pertain to the patients, and (4) the donations of charity organisations or other persons, and individuals, not involved directly in a specific transplant process.

The actual **Finnish** regulation is unknown, but some claim that the living donor should be free of charge so that financial circumstances will not prevent donation. They suggest that the employer pays the donor’s salary during the time the donor is unable to work; this means the daily allowance under the **Health Insurance Act** can be paid to the employer instead of the donor. The overall aim is to reduce the costs incurred by the living donor.

### 7.2 Insurance

With respect to the donor’s insurance, Switzerland can serve as a “gold standard”: It demands the surgeon who removes an organ from a living person to ensure that the person concerned is insured against any other potential serious consequences connected to the organ removal. This rule holds the insurer liable. The insurer must, in any case, compensate the recipient’s costs for her illness if no LOD is available. Additional details have been specified by the Federal Council in Art. 11 **Transplantation Ordinance**.

The German regulation can, after being clarified according to the following, be seen as the second best social security solution. It stipulates that every living organ donor has a right to be covered by the recipient’s health insurance company, especially to receive medical treatment, prior- and post-care, rehabilitation, travel costs and sick pay in the amount of his net loss of earnings. The insurance coverage of the social accident insurance is also extended. The social accident insurance is responsible for covering all damages to one’s health that exceed those normally caused by the donation or that are causally connected to the LOD.

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313 Sec. 120 II **General Social Insurance Law**.

314 Information from S. Füszl.

315 Art. 9, 1 Law on Harvesting and Transplanting Human Organs and Tissues.

316 Ibid., Art. 9, 2.

317 Art. 29 Law on the Transplant of Human Organs, Tissues and Cells.


320 Ibid., Art. 14, 2.

321 Draft of New German Regulation, Communication by the Ministry of Health, March 2012.
7.3 Reimbursement

A best practice regulation should explicitly clarify that all the donor’s possible expenses resulting from the LOD have to be reimbursed. The results of a survey made by WP 2 of EULOD, which included 113 kidney transplant units from 25 European Union Member States and 15 Non-member States (i.e. 40 countries in Europe) and 39 liver transplant units from 18 European Union Member States and 6 Non-member States (i.e. 24 countries in Europe), show that the current situation is insufficient because 54% of the kidney donors, and even about 70% of the liver donors, were not reimbursed.

In Switzerland, the recipient’s insurance company is responsible for all costs and for an “appropriate compensation for loss of earning or other expenses incurred by the donor in connection with removal.” In addition, Sec. 12 Transplantation Ordinance addresses the issue of expense allowance. The donor is compensated for all expenses she has in connection to the donation. This includes travel expenses, the costs she had with respect to the clarification of her being suitable as living organ donor, lifelong check-ups and any costs the donor may incur if she requires assistance, either personal assistance at home for herself or for others if she is their primary caretaker. The duties just stated also exist if the removal or donation cannot be performed. Swiss regulation considers cases where the recipient’s insurer is unknown. If the recipient’s insurer is unknown, the Confederation has to bear the costs. Since this regulation is extensive and protects the donor adequately, yet practicable and clear, a best practice proposal should follow the Swiss approach.

IV Summary of the best practice proposal

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) proce-
dure 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. 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.

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. 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 recommend-
able 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 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.”

All in all, the best practice proposal considered all issues of LOD in need of regulation and achieved extensive unification.
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Organ Trafficking, Organ Trade. Recommendations for a More Nuanced Legal Policy

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Introduction

By the twenty-first century, neither the number of available organs, nor the infrastructural and financial means could keep pace with the increasing need and the technological capacity for transplantation in the developed countries. National waiting lists have become full and long, and the number of people who died while waiting in the line has also increased. Furthermore, globalization created tension between developed and less developed countries, which resulted division between “organ recipient” and “organ donor” countries. Patients’ mobility has also increased and in many countries patients no longer feel bound to the capacity of one health care sector. It is easier to travel and it is no longer regarded as an exceptional luxury to seek health care beyond the national frontiers.

During our two year term project, in our work package within the EULOD project we attempted to map and to analyze laws, practices, cases, problems with regard the violation of organ transplantation laws. From the minor violation of selecting donor for the recipient to major and severe forms of violation of human rights, such as organ trafficking cases were collected and analyzed. We also examined selected laws and practices in order to develop recommendations which may serve for legislation, ethics committees and further research.

This chapter highlights different legislative and law enforcement strategies that could be employed in reducing and eliminating organ trafficking in the European region. The focus will be put both on the perpetrator of the crime and on its victim, while scrutinizing how the obligation of the states to reach this end is fulfilled.

Before going into it, it is important to emphasize the difference between an illegal organ sale, wherein organs are purchased from living donors or extracted from corpses and then transported for sale, quite often to different countries, and the practice of human trafficking for the purpose of organ removal, which usually involves transport of the “donor” followed by violent removal and even his/her death. When it comes to law enforcement strategies, this distinction becomes crucial since, although both are global phenomena, so far only human trafficking for organ removal has been fully outlawed on the universal and the regional levels. Namely, human trafficking for organ removal and organ trade include both a domestic and an international dimension, which makes these illegal practices an issue of local and global concern and a subject of domestic and international legal regulations. A lack of universal agreement on what constitutes organ trade and insufficient information from official sources so far have prevented the efforts to ban organ trade on the international level. This, however, should be soon changed, since on the European level much emphasis has already been put on drafting a new criminal law convention against trafficking in human organs – while there are also strong voices lobbying for adopting similar convention on the universal level. Due to the current differences, however, legislative and law enforcement strategies to combat trafficking in human beings for organ removal and those to combat organ trade will be addressed separately in this chapter.

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Human Trafficking for Organ Removal and Organ Trade in Europe

The news headlines coming from different parts of the world about organ trafficking confirm Michael Bos’ warning that organ trafficking “is all about money, not patients.”4 In one of the recent reports an extensive Southeast European network is uncovered. According to the investigation by the German weekly Spiegel, there are Israeli, Turkish, Belarusian, Moldovan, and German agents involved in organ trafficking through Kosovo.5 Among other charges, it is alleged that the Priština-based Medicus Clinic is sending human organs from the black market to clinics across Germany.6 There is already an ongoing trial in the so-called Medicus Clinic case before the District Court of Priština, against seven defendants who face charges of human trafficking for organ removal, organized crime, unlawful exercise of medical activity, including illegal organ transplants, and abuse of official position or authority.7 The investigation concerning these alleged crimes was launched in 2008 when a young Turkish man collapsed at the Priština airport after donating a kidney to an Israeli man.8 In addition, separate investigations are pending with regard to organ trafficking during the armed conflict in Kosovo. The Serbian War Crimes Prosecutor Office, for example, has launched an investigation in the case Trafficking in Human Organs, indicating that the crimes were committed from 1998 to 2001.9 The Council of Europe appointed a Special Rapporteur Dick Marty who, late in 2010, drafted the report on Inhuman Treatment of People and Illicit Trafficking in Human Organs in Kosovo.10 The Parliamentary Assembly of the Council of Europe adopted a resolution based on the report and requested follow-up investigations.11 In direct response to the Report, EULEX (European Union Rule of Law Mission) has opened an investigation and recently appointed US prosecutor John Clint Williamson to run it.12

The developments in Kosovo brought organ trafficking at the forefront of Europe’s concern. Despite the fact that most of the European countries have signed and ratified the European Convention on Action against Trafficking in Human Beings (Anti-Trafficking Convention), the most comprehensive international anti-trafficking regulation, and despite the fact that organ trade in all of the European countries is illegal, it appears that organ trafficking, in its varied manifestations – both trafficking in persons for organ removal and organ trade – persists and prevails in many parts of Europe and may even be increasing in some areas such as the former Soviet Union and South East Europe. The crime is blossoming due to insufficient regular supply – according to the aforementioned report by Spiegel, 40,000 seriously ill patients, in Europe alone, are waiting for a new kidney, which is still the most sought-after organ.13

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6 Ibid.
7 See the Ruling Confirming the Indictment, District Court of Priština, KA 278/10, P 309/10 and KA 309/10, P 340/10 at www.eulex-kosovo.eu/en/judgments/CM-District-Court-of-Pristina.php (last accessed on September 16, 2012).
9 The War Crimes Prosecutor Office of the Republic of Serbia, Trafficking in Human Organs, KTTR 33/08, p. 4. The file was inspected exclusively for the academic purposes.
Legislative and Law Enforcement Strategies to Combat Human Trafficking for Organ Removal

Trafficking in persons for organ removal is a form of trafficking in human beings that is currently banned both on the international and domestic level. It is not only an act of an organized and transnational crime, but also the practice that leads to direct infringement of a number of the victim’s rights, including the right to life, the right to human dignity, freedom of movement, the prohibition of torture and other cruel, inhuman and degrading treatment, the right to health and the prohibition of discrimination. For the purpose of law enforcement strategies, the fact that this practice has been assimilated with slavery is not without merits: “Trafficking in human beings is the slavery of our times. Victims are often recruited, transported or harbored by force, coercion or fraud in exploitative conditions, including sexual exploitation, forced labor or services, begging, criminal activities, or the removal of organs.”14 Thus, extremely similar to the classical forms of slavery, trafficking in human beings requires international measures similar to those once applied to eliminate the practice of slavery.15

International documents specifically addressing trafficking in human beings list measures that states have to adopt in combating this illegal practice, the most important being those listed in the UN Trafficking Protocol (the Palermo Protocol) which supplements the UN Convention against Transnational Organized Crimes, and the aforementioned European Anti-Trafficking Convention. Since recently, the standards set in the European Court of Human Rights’ case law also impose positive and negative obligations on the European states to be undertaken in order to reduce and eliminate human trafficking.16 Finally, among different EU documents, the brand new EU Strategy towards the Eradication of Trafficking in Human Beings 2012–2016, released in June 2012, lists the measures and identifies top priorities the EU should focus on in order to address the issues in trafficking in human beings.17 The measures envisaged on both international and domestic level testify that the progression has been made from approaching the problem with an exclusive focus on the punishment of the perpetrator to focusing on the rights and interests of the victim from a more holistic perspective.18

Thus, the Palermo Protocol and the Anti-Trafficking Convention require from the states to criminalize trafficking in human beings, including trafficking for organ removal, adopt comprehensive prevention programs, aid victims and respect their human rights and interests as well as to cooperate with other states in eliminating this modern evil. In its landmark 2010 ruling in the Rantsev v. Cyprus and Russia case, the European Court of Human Rights observed that the Palermo Protocol and the Anti-Trafficking Convention refer to the need for a comprehensive approach to combat trafficking which includes measures to prevent trafficking and protect victims, in addition to measures to punish traffickers.19 According to the Court, such measures range from raising awareness about the phenomenon of human trafficking, training law enforcement and immigration officials on issues related to human trafficking, implementing administrative measures to regulate the operation of businesses that cover up human trafficking, and instituting necessary changes in the policy

16 Among many, see the landmark case Rantsev v. Cyprus and Russia, Judgment from January 7, 2010.
17 See EU Strategy (2012).
19 Rantsev v. Cyprus and Russia, par. 289.
Organ Trafficking, Organ Trade. Recommendations for a More Nuanced Legal Policy

and the law related to immigration, criminalization, investigation and prosecution of all aspects of trafficking, to practically and effectively protecting victims’ rights. The EU Strategy towards the Eradication of Trafficking in Human Beings 2012–2016, identifies the following five policy measures aimed at eliminating trafficking in human beings: identifying, protecting and assisting victims of trafficking; stepping up the prevention of trafficking in human beings; increased prosecution of traffickers; enhanced coordination and cooperation among key actors and policy coherence; increased knowledge of and effective response to emerging concerns related to all forms of trafficking in human beings.

Despite of these normative and judicial developments, traffickers, including those who engage in this lucrative practice for organ removal, still mostly operate with impunity. Several factors contribute to the undisturbed continuation of their businesses: anti-trafficking regulations are not effectively harmonized; their implementation is inconsistent; while government officials and law enforcement institutions close their eyes on this practice or even remain involved in it. The Medicus Clinic case in Kosovo illustrates all facets of this tragic business. Additionally, according to INTERPOL, an ageing population and increased incidence of diabetes in many developed countries is likely to increase the need for organ transplants and make this crime even more lucrative.

What can be done to make prohibition on human trafficking for organ removal more effective? In what follows, some possible measures that fit well in the framework of the EU Strategy towards the Eradication of Trafficking in Human Beings 2012–2016 are going to be further elaborated.

In the realm of law and order, much ink has been spilled in attempts to emphasize the need to adopt adequate legislation, impose punishments on offenders, strengthen police cooperation and improve the number of prosecutions and convictions of traffickers. For the purpose of this chapter, one can assert that such policy-oriented measures are providing grounds for effective investigation in order to eliminate non-impunity for traffickers and increasing governmental cooperation in law enforcement, represent the way forward in achieving accountability for traffickers. Consider the following.

When a person is trafficked from one state to another, trafficking offences may occur in the state of origin, any state of transit, and the state of destination. As a consequence, it is a fundamental question which criminal jurisdiction is affected and involved and it tests the limits of state sovereignty and the role the international legal order can play. In order to secure that none of the traffickers remain unpunished and make fights against this illegal practice more effective, the states should be encouraged to employ different jurisdictional tools.

The first is the territorial jurisdiction, which is the most common and it is specified in the Anti-Trafficking Convention: member states are required to establish jurisdiction over any trafficking offence committed in its territory. In Rantsev, the European Court of Human Rights concluded that the obligation to investigate alleged trafficking offences was incumbent on all States under Article 4 of the Convention.

21 EU Strategy (2012).
24 The term jurisdiction, whether it applies to civil or criminal matters, includes the powers to prescribe, adjudicate, and enforce. It also includes the means by which the exercise of jurisdiction is obtained over a person. See M. Cherif Bassiouni, Universal Jurisdiction for International Crimes: Historical Perspectives and Contemporary Practice, Virginia Journal of International Law, vol. 42, no. 1 (Fall 2001): 81–162.
25 See Article 31 (a) (b) (c) of the Anti-Trafficking Convention.
26 Rantsev v. Cyprus and Russia, par. 288.
The second is extraterritorial jurisdiction also specified in the Anti-Trafficking Convention: applying extraterritoriality principle, states would be in a position to establish jurisdiction over its citizens who have committed the crime of human trafficking for organ removal outside of its territory or against the perpetrators who have committed this crime against their citizens in the foreign country.²⁷ Allowing the enforcement state to extend extraterritorially in cases of a valid legal nexus would secure that no offender evade criminal investigation.

The third jurisdictional tool – universal jurisdiction – is the most controversial, but at the same time potentially the most effective jurisdictional tool to prevent impunity for international and transnational crimes such as human trafficking for organ removal. Universal jurisdiction allows states to claim criminal jurisdiction over persons whose alleged crimes have been committed outside its boundaries, regardless of nationality, country of residence or any other relation with the prosecuting country. The rationale behind the exercise of such jurisdiction is:

1. no other state can exercise jurisdiction on the basis of the traditional jurisdictional grounds;
2. no other state has a direct interest; and
3. there is an interest of the international community to enforce.²⁸

By exercising universal jurisdiction the state acts as a surrogate for the international community and conducts investigation against persons who are *hostis humani generis*.²⁹ Universal jurisdiction is most often reserved for the most serious international crimes, including genocide, war crimes, crime against humanity, slavery, torture and some other international crimes that have risen to the level of jus cogens, which implies the existence of universal jurisdiction. However, universal jurisdiction is not without flaws: it can produce conflicts of jurisdiction between states that can undermine world order, subject individuals to abuses of judicial processes and human rights violations. It may also be perceived as hegemonic jurisdiction exercised mainly by some Western powers against persons from developing nations.³⁰

After the European Court’s ruling in *Rantsev*, it seems that necessary ground implying universal jurisdiction for human trafficking, including trafficking for organ removal, was established. Although in rather contradictory manner the Court concluded that Article 4 of the European Convention on Human Rights and Fundamental Freedom is a tool to considering the issue of trafficking³¹, it nevertheless recognized two important points which could encourage states to claim universal jurisdiction with regard to human trafficking for organ removal. The first concerns the fact that the Court assimilated trafficking in human beings with slavery.³² Although the related provisions in all the treaties relevant to slavery and slave-related practices reflect the principle of *aut dedere aut judicare*,³³ customary international law and the writings of scholars have recognized slavery and slave-related practices as a jus cogens international crime, which may authorize states to practice universal jurisdiction in their efforts to confront these practices.³⁴ Namely, what actually urges the recognition of universal jurisdiction is the maxim *aut dedere aut judicare*, which refers to the obligation of the state either to prosecute the trafficker or extradite him/her to the state having jurisdiction. If one has in mind that the Anti-Trafficking Convention recognizes the principle *aut dedere aut judicare*, then the recognition of universal jurisdiction represents a means of achieving the ultimate

²⁷ See Article 31 (d) (e) of the Anti-Trafficking Convention.
²⁸ For a detailed discussion see Bassiouni (2001).
²⁹ Ibid., p. 11.
³⁰ Ibid., p. 55.
³¹ The Court has refused to rule on whether trafficking in human beings amounts to some of the practices prohibited under Article 4 of the European Convention for the Protection of Human Rights and Fundamental Freedoms – “slavery”, “servitude” or “forced labor”, but instead, simply concluded that human trafficking as defined in Article 3(a) of the Palermo Protocol falls within the scope of Article 4 of the Convention.
³² *Rantsev v. Cyprus and Russia*, par. 280-281.
³³ For a detailed discussion on the issue of jurisdiction in slavery conventions see Bassiouni (2001), pp. 22–25.
³⁴ Ibid., p. 25.
goal – accountability of traffickers. In fact, the Anti-Trafficking Convention in a way nudges the state to refer to universal jurisdiction by its Article 31 (5), which specifically provides that “without prejudice to the general norms of international law, this Convention does not exclude any criminal jurisdiction exercised by a Party in accordance with internal law”.

Second, although the Court in Rantsev did not mention that the duty to establish universal jurisdiction arose under Article 4 of the Convention, its aforementioned conclusion that Article 4 of the Convention imposed on all States the general obligation to investigate the crime could be interpreted in favor of establishing universal jurisdiction in addition to other jurisdictional grounds. The Court’s reference to the objective of the Palermo Protocol concerning the states’ obligation to adopt a comprehensive international approach to trafficking in the countries of origin, transit and destination, additionally favors this solution.35 The negative effects of universal jurisdiction could be mitigated by domestic rules that would allow adherence only to conditional universal jurisdiction in cases when an alleged perpetrator is on the territory of the enforcement state and no other state can exercise jurisdiction on the basis of the traditional jurisdictional grounds or has a direct interest in conducting investigation.

Another tool for achieving accountability of traffickers is intensifying cooperation among states in fight against trafficking in human beings for organ removal. Since recently, cross-border cooperation in suppressing human trafficking has become a duty of the European states – failure to obey it may amount to a violation of Article 4 of the European Convention for the Protection of Human Rights and Fundamental Freedoms. Namely, the European Court of Human Rights has concluded that member states are subject to a duty in cross-border trafficking cases to cooperate effectively with the relevant authorities of other States concerned in the investigation of trafficking events, which occurred outside their territories.36 The Court noted that such a duty is in keeping with the objectives of the member States, as expressed in the preamble to the Palermo Protocol, to adopt a comprehensive international approach to trafficking in the countries of origin, transit and destination and that it is consistent with international agreements on mutual legal assistance.37

The need for making states cooperation in fight against human trafficking mandatory arose from a simple fact that “currently, countries police within their own borders what has become a transnational market.”38 Since trafficking in human beings for organ removal is a form of organized and transnational crime, only broad cooperative measures implemented globally, regionally and on the national level could produce effective results in combating trafficking and alleviating the roots of its cause – “poverty, underdevelopment and lack of equal opportunity” (Article 9 of the Palermo Protocol). Among many traditional tools of cooperation in criminal matters, it seems that strengthening international police cooperation aimed at better exchange of information between countries of origin and countries of destination could eliminate a high number of unreported cases. This can be achieved through already established networks such as INTERPOL, EUROPOL and SECI (Southeast European Cooperative Initiative Regional Center for Combating Trans-Border Crime).

Finally, in law and order area, complying with the findings of GRETA, which is the European monitoring system established in accordance with Article 38 of the Anti-Trafficking Convention, may make the states more efficient in suppressing human trafficking for organ removal. GRETA draws up country evaluation reports containing an analysis of the implementation of the Anti-Trafficking Convention by each Party and proposals for further action. On the basis of GRETA’s

35 Rantsev v. Cyprus and Russia, par. 148, 288.
36 Ibid., par. 288.
37 Ibid.
reports, the political pillar of the monitoring mechanism, the Committee of the Parties, may adopt recommendations concerning the measures to be taken to implement GRETA’s conclusions.39

Trafficking in human beings, including trafficking for organ removal is not only the issue of law and order. Above all, it is a human rights issue because it denies its victims virtually all rights protected by international human rights law. Although both international community and the national governments have made a substantial progress in achieving better protection for victims, it seems that one particular policy measure – immunity from prosecution for victims of trafficking has not attracted enough attention. Namely, Article 26 of Anti-Trafficking Convention envisages that “Each Party shall, in accordance with the basic principles of its legal system, provide for the possibility of not imposing penalties on victims for their involvement in unlawful activities, to the extent that they have been compelled to do so”. There are two policy measures that could be undertaken to achieve this goal. First, all states members of the Anti-Trafficking Convention should provide for an explicit right to immunity from prosecution for victims of trafficking in human beings on the grounds indicated in Article 26 of the Convention. Second, since the omission of the non-punishment provision represents a substantial oversight in the Palermo Protocol, the countries members of the Protocol should initiate the amendment providing for an explicit legal protection against criminal prosecution of the victims of trafficking, as it has been already envisaged in Article 5 of the UN Protocol against the Smuggling of Migrants by Land, Sea and Air, which like the Trafficking Protocol, also supplements the UN Convention against Transitional Organized Crimes.40

Legislative and Law Enforcement Strategies to Combat Organ Trade (Commercialism)

The Ovideo Convention states a categorical ban on the commercialization of organ donation in Article 21 by saying “The human body and its parts shall not, as such, give rise to financial gain.” The convention is based on broad consensus in Europe as more than twenty countries have ratified it so far. It follows from the text that both commercialization and commodification are covered by this prohibition. The prohibition is restated in the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Transplantation of Organs and Tissues of Human Origin. The Protocol also prohibits the advertising of the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage.

In the Explanatory Note of the Convention it is clarified that under Article 21 of the Convention organs and tissues, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital. However, certain technical acts which are performed on the basis of these items may legitimately give rise to reasonable remuneration. For instance, this Article does not prohibit the sale of a medical device incorporating human tissue as long as the tissue is not sold as such. Further, this Article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income.

At the EU level, the European Commission has urged addressing ethical and legal issues concerning organ transplantation. One of the most important legal instruments was adopted in 2010, the Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

Despite remarkable consensus that organ trade is unethical and illegal practice and is prohibited virtually in all countries except in Iran, the shortage in organs has opened the door for criminals to use this circumstance for making organ trade a global, highly profitable criminal activity. Thus, “transplant ethics has been on a slippery slope almost since transplants began”.\textsuperscript{41}

Organ trade or transplant commercialism is defined in the Declaration of Istanbul as “a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.” Commodification has been further explained as to refer to the production of a good or service for a profit.\textsuperscript{42} Almost every single country endorses the non-commerciality principle in organ transplantation and has implemented it into their national laws. As it has been frequently underlined in this book, the principle of non-commercialization of the human organs has been re-affirmed by the Council of Europe and by the European Union, as well.

Like trafficking in human beings for organ removal, organ trade is also a type of an organized and transnational crime that includes both international and domestic dimensions. Transplant transactions require participation of different actors, starting from medical directors of transplant units, hospital and medical staff, technicians in blood and tissue laboratories, dual surgical teams working in tandem, nephrologists, postoperative nurses, to travel agents and tour operators to organize travel, passports and visas, medical insurance agents, kidney hunters to recruit donors locally or internationally from among vulnerable and marginalized populations, religious organizations and charitable trusts which sometimes call upon organ brokers, and patient advocacy organizations which sometimes call upon organ brokers.\textsuperscript{43} This is why the commission of this crime can be distinguished in terms of the sectors from which the perpetrators derive.

When it comes to law enforcement, it is general view that surgeons, medical administrators, organ brokers, buyers or sellers are rarely subject to law enforcement measures. Basically, two reasons contribute to this fact. First, while the trafficking in human beings for the purposes of organ removal has been fully covered by definitions and policy measures in national legislation and international documents, “there is a legal vacuum for the traffic in organs”.\textsuperscript{44} While the Declaration of Istanbul defines and differentiates trafficking from commercialism, it does not offer enough guidance to the prohibition enforcement policy. Second, as it has been rightly noted, “a combination of shame, fear and guilt keep donors and recipients silent, and thus the crimes are hard to investigate and prosecute”.\textsuperscript{45}

In the rest of this chapter, we will underline some necessary law enforcement policy measures to combat organ trade in law and order area. Besides lobbying for criminalization on both national and domestic level, having in mind that the governments are obliged to protect human rights of its citizens and all others within their jurisdiction, we will briefly explain why criminal immunity for impoverished and vulnerable sellers should become mandatory victim’s protection measure with regard to organ commercialization.

It is in the common interest of all European states to support the work of the Committee of Experts on Trafficking in Human Organs, Tissues and Cells, set up under Article 17 of the Statute of the Council of Europe and in accordance with Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies. For the purpose of this chapter, it is important to emphasize

\textsuperscript{41} Miran Epstein, The Organ Crisis. Available at www.project-syndicate.org/commentary/the-organ-crisis (last accessed on September 16, 2012).


\textsuperscript{44} Amelia Mathias citing Marja Ruotanen, COE Director of Cooperation, in International Convention Needed to Combat Organ Trafficking, at http://jurist.org/paperchase/2009/10/international-convention-needed-to.php (last accessed on September 16, 2012).

\textsuperscript{45} Panjabi (2010), p. 6.
that among its various tasks, the Committee is to draft a criminal law convention against trafficking in human organs and, “if appropriate, to ensure that the draft convention and its possible draft additional protocol provide added value, in particular when addressing criminalization of trafficking in human organs, prevention of trafficking in human organs, assistance to victims and international co-operation.”

So far, it is known that under Part II, the draft Convention against Trafficking in Human Organs “obliges the states to criminalize the illicit removal of human organs for transplantation or other purposes, use of illicitly removed organs for purposes of implantation or purposes other than for implantation, implantation of organs outside of the domestic transplantation system, illicit solicitation, recruitment, offering and requesting of undue advantages, as well as preparation, preservation, storage, transportation, transfer, receipt, import and export of illicitly removed human organs. In law and order area, the draft Convention envisages obligations of the states to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, if appropriate, the possibility of carrying out financial investigations, undercover operations, controlled delivery and other special investigative techniques.” Like other anti-trafficking instruments, this Convention is not going to be self-executed, but rather, it will require from the states to adopt measures in national legislation in accordance with its provisions.

Some countries have already adopted necessary measures to criminalize organ trade and associated practices of solicitation, recruitment, offering and requesting of undue advantages with regard to transplantation process. For example, the provisions in Sections 2, 7 and 32 (2) of the Dutch Law on Organ Donation reflect the non-commerciality principle in transplant medicine in the following ways:

Section 2 states: “Consent given for the removal of an organ, given in return for payment amounting to more than the costs (including loss of income) incurred by the donor as a direct result of the removal of the organ, shall be invalid”.

Section 7 states: “Neither the donor nor any other person from whom consent is required pursuant to Part 2 of this Act shall receive any payment other than compensation for the costs referred to in Section 2.”

Section 32 (2) states: (a) “a party who deliberately causes or encourages a third party to consent to the removal of an organ during his lifetime in return for payment in excess of the costs referred to in Section 2, or to contravene the provisions of Section 7; (b) a party who openly offers payment in excess of the costs referred to in Section 2 for the receipt of an organ, or who puts himself forward as a donor in return for such payment, or who offers services which involve activities which are punishable under this Section 32, this subsection 2, under a.; [...] shall be punishable by up to one year in prison or a fourth-category fine.”

The Serbian Organ Transplantation Act of 2009, in addition to organ trade has also criminalized two offences concerning a violation of free consent requirement for organ donation: the first relates to organ removal from living donor by force, coercion or deception, and the second relates to implantation procedure and organ removal without or against the will of the recipient or the deceased person. Particularly comprehensive is the provision of Article 79 that incriminates organ trade:

(1) Whoever, for any kind of compensation, gives their organ or organ of another person for transplantation purposes or offers for compensation their organ or organ of another person for trans-

46 Plachta (2012).
47 Ibid.
plantation purposes, or recruits, transports, transfers, delivers, sells, purchases, mediates in the 
purchase or mediates in any other manner in organ transplantation or participates in transplant-
lation process which is subject of commercial trade, shall be punished by imprisonment for two 
to ten years.

(2) If the criminal offense referred to in paragraph 1 of this Article is committed against a juvenile, 
the perpetrator shall be punished by imprisonment for not less than three years.

(3) If the perpetration of criminal offense referred to in paragraph 1 and 2 of this Article, resulted in 
a serious bodily injury of the donor, the perpetrator shall be punished by imprisonment for three 
to fifteen years.

(4) If the perpetration of criminal offense referred to in paragraph 1 and 2 of this Article, resulted 
in death of the donor, the perpetrator shall be punished by imprisonment for not less than ten 
years.

(5) Whoever engages in committing criminal offences referred to in paragraph 1 to 2 of this Article 
or if the offence is committed by an organized group, the perpetrator shall be punished by im-
prisonment for not less than five years.

Besides criminalization of organ trade, it is essential for all states also to criminalize the instigation 
of, aiding, abetting or attempt to commit the offence.

Finally, among measures aimed at criminalizing, investigating and prosecuting for the offence of 
organ trade, measures related to the responsibility of the health care professionals are particularly 
important having in mind their essential role in this illicit practice. Thus, the provision of Article 27 
(2) of the Serbian Organ Transplantation Act expressly refers to ethical obligation of a health care 
professional to refuse to participate in transplantation procedure if he/she has any suspicion that an 
organ to be used for transplantation has been obtained through a commercial transaction:

A health care professional, involved in carrying out transplantation procedure, who 
suspects that an organ to be used for transplantation is a subject of commercial 
trade, must reject the participation in transplantation procedure and without undue 
delay, in oral or written form, inform the competent state authorities and the Bio-
medicine Bureau.

This significant novelty follows the 2006 World Medical Association Statement on Human Or-
gan Donation and Transplantation. According to above cited Article 79 (1) of the Organ Transplan-
tation Act, the ramifications of its violation could be serious and could lead to criminal responsibil-
ity of a health care professional for participation in transplantation process of an organ obtained 
through commercial trade.

We come now to criminal immunity for impoverished and vulnerable sellers. Basically, it is 
poverty that drives people to sell a body organ in case of no other options: “It is a manifestation of 
dire economic necessity, sometimes a means for an entire family briefly to eat and survive or pay 
off a debt to an assertive moneylender.”48 For vulnerably and impoverished donors the situation 
becomes even worse after illegal transplants. In its Recommendation 1611 (2003) the Council of 
Europe Parliamentary Assembly stressed that

“It is a matter of grave concern that following illegal transplants the donor’s state of 
health generally worsens in the medium term, due to the absence of any kind of 
medical follow-up, hard physical work and an unhealthy lifestyle connected to inad-

48 Panjabi (2010), p. 3.
Apart from long-term measures aimed at eliminating poverty, this situation urges immediate measures to be undertaken to secure access to health care and legal services for impoverished and vulnerable sellers, including legislative measures which will secure their criminal immunity unless they are not themselves engaged in organ trade as organ brokers. It is our view that criminal immunity for impoverished and vulnerable sellers does not undermine the principle of non-commercialization of the human organs nor the prohibition of financial gain with regard to organ transplantation, but only partially remedies their appalling situation caused by poverty and lack of equal opportunity.

**Terminology and Conceptual Problems**

In a time of economic crisis it is not easy to clarify what constitutes organ commodification, organ trade and organ trafficking. Furthermore, it is difficult to find the appropriate regulative policy, and proper safeguards for enforcing the already established legal standards. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (hereafter Declaration) is the first document, drawn up by the international transplant community that defines and condemns transplant commercialism, organ trafficking and transplant tourism. Its primary aim is to inform, inspire and promote ethical practices in organ donation and transplantation around the world. Building on the Universal Declaration of Human Rights and World Health Assembly Resolution 57.18, it aspires to achieve this aim by endorsing prohibition of transplant commercialism, tourism and trafficking of organs and penalization of those that aid or encourage it. The Declaration’s Custodian Group and four task forces have been established to implement and monitor its effects.

The Declaration, non-binding by nature, nevertheless has proven to have significant influence. Over one hundred transplant organizations endorse its principles. Countries including China, Israel, the Philippines and Pakistan have passed new legislation or strengthened existing laws that ban organ trafficking and organ sales.

This acclaimed success is for a large part due to the World Health Organization (WHO) and its Guiding Principles on Human Cell, Tissue and Organ Transplantation (hereafter Guiding Principles). Whereas the Declaration is intended to influence transplant professionals and societies, the WHO intends to influence governments. Both act in concert to address growing problems of transplant commercialism, transplant tourism and trafficking by strict prohibition and penalization.

The prohibitionist discourse in the Guiding Principles and Declaration has a predominant focus on prohibition (through legislation) of commercialism and trafficking, however the importance of enforcement of the crime is neglected. Furthermore, there is a discomforting lack of criminological and legal expertise about what exactly we are trying to prevent by prohibition. Commercialism and trafficking are presented as being equally problematic crimes. However, coercion and exploitation of donors (trafficking) differs from the sale and purchase of organs (commercialism). Both acts warrant a different policy approach. The Declaration’s Custodian Group and WHO, in their

49 See Council of Europe Parliamentary Assembly, Recommendation 1611 (2003), at assembly.coe.int/Main.asp?link=/Documents/AdoptedText/ta03/EREC1611.htm, (last accessed on September 16, 2012).


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discourse on prohibition, do not take account of this distinction. They can improve their strategy to prevent and deter commercialism and trafficking in a number of ways. In the following paragraphs we explain why and how.

The WHO first declared the prohibition of organ trade in 1987, affirming that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights. The WHO Guiding Principles state the reason why organ sales are prohibited. The Commentary to Principle 5 states: “Payment for […] organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others.”

The organ trade prohibition must be seen in context of when it was formed: at a time when there was no shortage of organs and organ trade and trafficking offences barely occurred. Back then, the prohibition was successful in its aim to prevent trade and trafficking, simply because the root cause of the crime (organ shortage) was not as rampant as it is now. The prohibition worked, not only as a preventative mechanism, but also as a universal norm that organs were not to be used commercially. Almost every single country endorses the non-commerciality principle in organ transplantation and has implemented it into their national laws.

Since the nineties however, transplantation has become a victim of its own success, with demand for organs far outpacing their supply. Organs have become more valuable and profitable to sell. This leads to black markets that involve various actors who increasingly make use of organs’ high profitability.

Together with drugs, humans, arms, diamonds, gold and oil, organs are becoming the subject of an illegal multibillion dollar industry. A recent report by Global Financial Integrity estimates that the illicit organ trade generates illegal profits between $600 million and $1.2 billion per year. It ranks the trade in human organs on number ten of the illegal activities studied in terms of illegal profits made. The report further states that profits from these illicit markets are making their way to transnational crime syndicates through vast international trade networks. These networks take advantage of globalization and new communication and transportation technologies. Key to the growth and success of global criminal networks is their flexibility and versatility, which have expanded their activities to a wide diversity of legal and illegal fields.

Indeed, an increasing number of organ trafficking rings are globally active and involve actors who operate in different countries from where recipients and donors are recruited. Organ trafficking accounts come from all over the world, including Egypt, India, South Africa, the Philippines, Israel, Colombia, the Balkan Region, Turkey and Eastern Europe.

53 Ibid.
including the US, the UK, Macedonia and Canada report on patients leaving to well-known organ exporting countries who allegedly buy organs on the black market.\(^58\)

Only in very few cases have crime control efforts led to accusations by victims and prosecutions of the accused. Indeed, organ trafficking may be one of the most difficult crimes to detect. Moreover, its enforcement is not a priority of local, national and international law enforcement institutions. The universal response to the crime is characterized by punitive condemnation through legislation but awareness and expertise on how to detect the crime and enforce the law is practically non-existent.

### Prohibition of Demand-Driven Crimes May Herald Significant Risks

Prohibition of demand-driven crimes is not new to the field of criminology. For centuries countries have been struggling to control criminalized, demand-driven activities often with limited effect.\(^59\) Disregarding evidence that crime does not readily respond to severe sentencing, legislatures have over the years repeatedly adopted a punitive ‘law and order’ stance. David Garland describes this ambivalent response as a form of *acting out*, which is to say that legislatures engage in a form of impulsive and unreflective action, avoiding realistic recognition of underlying problems.\(^60\) The reasons behind these repressive policies are often political: they are motivated by politically urgent needs to ‘do something’ decisive about crime, restore public confidence, illustrate good intention and demonstrate state control. These policies are seldom evidence-based, are not aimed at removing the root cause of crimes and do not acknowledge the risks that may arise.\(^61\)

A wealth of studies illustrates the resilience of demand-driven activities such as drug use, gambling, alcohol consumption and prostitution to prohibition.\(^62\) These studies also highlight how harms associated with these demand-driven crimes including violence, disorder and corruption are in fact caused by their prohibition.\(^63\) These studies show how 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.\(^64\) One illustration is the “war on drugs”. A recent report by the International Centre for Science in Drug Policy argues that enforced drug control in

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\(^{61}\) Ibid.

\(^{62}\) Ibid.


the US led to unintended, harmful consequences. Efforts in the US to suppress the sale and use of cannabis have substantially increased in the last years. The costs for stronger enforcement rose from $1.5 billion in 1981 to more than $18 billion in 2002. The report’s authors claim that despite increased repression rates of violence, organized crime, the availability of illegal cannabis and the number of users substantially increased. These conclusions on the failures of the system are in line with reviews of evidence from a global perspective. The authors advise alternatives to prohibition, such as decriminalisation and regulation. Indeed, evaluation of more liberal drug and prostitutions policies involving a harm-reduction approach in countries such as the Netherlands have shown that the social harms within regulated markets are lower than in prohibited markets.

Despite substantial differences in nature between demand-driven crimes including the organ trade, drug trade and prostitution, the ways in which most states attempt to control them are similar. Unintended implications that may arise from prohibition of crimes such as the drug trade may be equally relevant and applicable to organ trade. First, prohibition of organ trade and drug trade has the similar effect of making them more worth and thus more profitable. Second, arguments often made in favour of regulating the drug- and organ trade share the view that legalization is likely to reduce social harms inflicted upon vulnerable groups.

We believe that the risks known to arise despite or as a result of prohibition of demand-driven crimes should be taken seriously.

The Declaration of Istanbul in our view takes little account of the possible implications that prohibition of organ trade may herald. Their response to organ trade and trafficking has little to no recognition for the limits of crime control and limited acceptance of exploring alternative polices that possibly herald less harmful effects. Rather, their belief seems to be that prohibition will take away the problem and decrease illegal activity. The passing of legislation against organ trade and trafficking is proudly announced and expected to be followed by successful tackling of the problem. One example of ineffective prohibition occurs in Pakistan that as a result of the Declaration lobby passed an ordinance in 2008 prohibiting foreign patients from purchasing transplants there. Despite the initial hope that the ordinance would prevail, a recent Pakistani newspaper article admits how despite the new law, Pakistan is being “sucked back into the vortex of kidney trade and transplant tourism.”

We think that the international co-operation should be strengthened to make sure that the current prohibitionist strategy of organ trade is not becoming ineffective and symbolic.

The relevance and limits of the Declaration of Istanbul

To assess what works, we need to get our definitions straight. Organ trade takes on a wide variety of forms: only after we agree on the definition of commercialism and trafficking, and on what we find condemnable, can we agree on their prohibition. Putting a price on organs (commercialism) is different from coercing someone into selling one (trafficking).

The Declaration correctly defines and differentiates trafficking from commercialism, yet it does not mention how both acts should be approached by policy. However, policies aimed to suppress

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67 MacCoun and Reuter, op. cit.


69 MacCoun and Reuter, op. cit.

70 Delmonico, op. cit.

or reshape an illegal trade or market work differently from policies addressing coercion and other harms associated with trafficking. Evaluative studies have shown that criminalization of commercialism is likely to reinforce trafficking.\(^{72}\) Indeed, it has been argued that “there is much more scope for exploitation and abuse when a supply of desperately wanted goods is made illegal.”\(^{73}\) We therefore claim that the Declaration should clearly differentiate between policies needed to address commercialism and those needed to address trafficking.

First of all, to tackle and prevent organ trade, the root cause of the problem (organ scarcity) should be addressed. This ultimately means boosting organ supply. One such strategy that the Declaration already strongly supports is to help governments implement deceased donation programmes to increase deceased donation rates and achieve self-sufficiency. Such initiatives are being conducted in the Balkans\(^{74}\) and Black Sea region\(^{75}\) with the support of the Custodian Group, the WHO and European Union. Yet promotion of deceased donation alone is not enough to fill the gap between demand and supply of organs.

Although priority should be given to the better use of the organs from cadavers, still WHO and other relevant organizations should also encourage the increase of living donation. They should do so by explicitly stating the need to promote living donation in the text of the Declaration and Guiding Principles. International organizations and NGOs’ should furthermore encourage governments to remove unjustified restrictions regarding living unrelated or anonymous donation to make alternative living donation programmes possible.\(^{76}\) Such programs should be implemented in consistency with international standards to ensure quality and safety of donors and recipients. Current restrictions to unrelated donation are based on the belief that living unrelated donation induces trade. However, there is no evidence of illegal trade in countries with well-organized systems allowing for high numbers of living unrelated donation such as in the US, the Netherlands, Norway and the UK. As it follows legislators should examine alternative safeguards to ensure that organ donation will not be commercialized while extending the possibilities for donation not only among genetically related family members.

A third example is to support regulated trials of incentives for donation.\(^{77}\) This asks for a more liberal approach by both the WHO and the Declaration towards incentives. Incentives for donation may perhaps be promising examples of a harm-reduction approach. The Declaration should provide scope for governments to explore ways to increase donation through incentives. As it was suggested by Sándor\(^{78}\) priority should be given to ethical incentives (such as acknowledgment of the efforts of the living organ donors) and incentives that may grant future health services in case of need but not in the *quid pro quo* manner. So for instance in case the organ donor may need future expensive health service (such as transplantation e.g.) may be given priority based on his/her previous generosity but the need for that health care service should be not yet certain at the moment of

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\(^{72}\) MacCoun and Reuter, op. cit.


\(^{74}\) The Transplantation Society. Balkan Initiative in Deceased Donation Meeting, Skopje, Macedonia Tribune 2011 April.


\(^{77}\) Erin and Harris, op.cit.

donation. In this way the person is not given kidney for material benefits (as at the moment of the
donation he/she is not sure whether she will need it) but fairness would dictate to take into account
such a generosity in using health services in the future.

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 is probably the best
and most powerful incentive for organ donation. If someone suffers from the prospect of losing a
close relative, organ donation seems to be a sacrifice worth doing. Therefore, if substantial addi-
tional 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 organ donors if they are
unable to receive the necessary health care service when they need it later in their lives and poss-
sibly die in the lack of financial support. Nevertheless, their future health care needs should be un-
certain at the moment of donation, and should not be taken as a condition for the act of donation.

Finally, we think that international strategy to combat organ trafficking should be improved by
prioritizing enforcement. There is no doubt that organ trafficking is and should remain prohibited
universally. The text of the Declaration already emphasizes the prohibition and penalization of acts
including brokering and other (medical) practices that aid or encourage trafficking. Indeed, organ
trafficking cannot occur without the involvement of a medical staff. A recent organ trafficking
network uncovered in South Africa illustrates the criminal involvement of medical staff, including
nephrologists, surgeons and administrative staff who were found guilty of performing over one
hundred illegal kidney transplants and receiving payments for them. This case also demonstrates
the immense investment that is needed to eventually bring perpetrators to justice. It took investig-
gators seven years to succeed in gathering enough evidence to bring the case to court. However,
dedicated investigations and efforts to identify collusion in hospitals and other criminal activities,
in short, the enforcement and police intelligence necessary to bring such cases to court, does not
exist in other countries. Organ trafficking case law is practically non-existent. Prohibition of organ
trafficking largely remains a paper exercise. Strict, legislative prohibitionist efforts, no matter how
sophisticated, are fruitless if they are not accompanied by enforcement by local, national and inter-
national policing agencies.

In order to achieve a consistent and effective prohibition of organ trafficking, legislation and law
enforcement must go hand in hand. As a result of our research, we have summarized our findings
in eleven recommendations.

**Recommendation 1:**
**Awareness Raising about the Crimes of Organ Trafficking Should Be Enhanced with the Involvement of Enforcement Institutions**

Greater awareness about organ trafficking can be reached by sharing information about organ traf-
ficking cases with INTERPOL, EUROPOL, UNODC, and local institutions such as national police
service agencies. Organ trafficking researchers and other experts could send their reports and
research findings to these target groups. Dissemination of information can occur through the com-
petent authorities and Member States of EU and UN bodies.

Enhanced collaboration between these partnerships can be encouraged by EU-funding mechan-
isms for research projects and cooperation actions, such as by the European Commission Home
Affairs Program. Fortunately, this programme started funding a three year research project called
“combating trafficking in persons for the purpose of organ removal” (the HOTT project) in 2012.
Other platforms for enhanced collaboration lie with the Council of Europe, the WHO and the

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79 Jean Allain, Commentary: Trafficking of Persons for the Removal of Organs and the Admission of Guilt of a South
OCSE. These organizations are known to have written organ trafficking reports, yet little collaboration exists between these organizations and law enforcement institutions. Toolkits for Member States and Competent Authorities should be developed that provide indicators for police personnel to identify organ trafficking activities.

Training of police investigators should be encouraged regarding evidence gathering of organ trafficking cases and know-how about the *modus operandi* of the actors involved, training of prosecutors and judges. The establishment of bilateral and/or multilateral cooperation in cross-border criminal procedures shall be encouraged.

Ideally, such considerations are best followed when close collaboration between the medical field and (international) criminal justice agencies is achieved.

Perhaps the greatest achievement for the WHO and Declaration of Istanbul will thus lie in bridging the gap between the medical field and the criminal justice realm. Indeed, the Declaration does not have a binding force but both bodies may be the most influential forces to stimulate governments into addressing enforcement strategies.

Starting from the fact that the crime of trafficking in human beings leads to direct infringement of a number of the victim’s human rights, including the right to life, the right to human dignity, freedom of movement, the prohibition of torture and other cruel, inhuman and degrading testament, the right to health and the prohibition of discrimination, and recalling that exploitation is viewed as fundamental to the trafficking experience, and having in mind Article 26 of the Council of Europe Convention on Action against Trafficking in Human Beings which envisages that “Each Party shall, in accordance with the basic principles of its legal system, provide for the possibility of not imposing penalties on victims for their involvement in unlawful activities, to the extent that they have been compelled to do so”,

**Recommendation 2:**
**Provide Non-Punishment for the Victims of Trafficking**

One of the major obstacles in enforcing the prohibition of organ sale and trafficking lies in the inaccessibility of victims. Therefore we think, that all states should provide for explicit right to immunity from prosecution for victims of trafficking in human beings on the grounds indicated in Article 26 of European Convention on Action against Trafficking in Human Beings.

Since the omission of the non-punishment provision represents a substantial oversight in the UN Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, the countries members of the UN Trafficking Protocol should initiate the amendment providing for an explicit legal protection against criminal prosecution of the victims of trafficking, as it has been already envisaged in Article 5 of the UN Protocol against the Smuggling of Migrants by Land, Sea and Air, which like the Trafficking Protocol, also supplements the UN Convention against Transitional Organized Crimes.

Affirming that the principle according to which the human body and its parts shall not, as such, give rise to financial gain, and stressing that the prohibition of financial gain with regard to organ transplantation is part of the legal *acquis* of the Council of Europe, but underlying the statement in the Council of Europe Parliamentary Assembly Recommendation 1611 (2003) that “it is a matter of grave concern that following illegal transplants the donor’s state of health generally worsens in the medium term, due to the absence of any kind of medical follow-up, hard physical work and an unhealthy lifestyle connected to inadequate nutrition and a high consumption of alcohol...”, and having in mind that the governments are obliged to protect human rights of its citizens and all others within their jurisdiction, which includes securing them access to health care and legal services, while at the same time addressing and eliminating causes of poverty.
Recommendation 3:
Provide Criminal Immunity for Impoverished and Vulnerable Sellers

All states should implement legislative measures which will secure criminal immunity for impoverished and vulnerable sellers and potential sellers of organs unless they are not themselves engaged in organ trade as organ brokers.

Having in mind that trafficking in human beings for organ removal is a form of an organized and transnational crime we stress that only broad cooperative measures implemented globally, regionally and on the national level could produce effective results in combating trafficking and alleviating the roots of its cause – “poverty, underdevelopment and lack of equal opportunity” (Article 9 of UN Trafficking Protocol). Therefore, to reduce human trafficking for organ removal the improvement of national law enforcement policies should embrace:

Recommendation 4:
Develop Law Enforcement Policies to Suppress Trafficking in Human Beings for Organ Removal

Adopting the measures to fight against trafficking in human beings including the trafficking for organ removal in accordance with the European Convention on Action against Trafficking in Human Beings and recommendations issued by GRETA, which is a body responsible for monitoring the implementation of the Convention by Contracting States.

Strict adherence to the principle aut dedere aut judicare: a state should make every effort either to prosecute the trafficker or extradite him/her to the state having jurisdiction. Adopting the legislative measures which would establish (a) extraterritorial jurisdiction for instituting the criminal proceedings against the perpetrator and (b) a conditional universal jurisdiction which would provide for prosecution by any state even in the absence of any connection between the state, the perpetrator and the victim, provided that the perpetrator is in custody of the state concerned (forum deprehensionis jurisdiction).

It is of utmost importance of strengthening international police cooperation aimed at better exchange of information between countries of origin and countries of destination through the established networks such as INTERPOL, EUROPOL and SECI (Southeast European Cooperative Initiative Regional center for Combating Trans-Border Crime) with an aim to eliminate a high number of unreported cases.

Recommendation 5:
Adopt measures for the explicit criminalization of organ trade

Having in mind that organ trade for the purpose of organ transplantation mainly exists due to shortage of organs, and that organ trade outside of national system is a widespread phenomenon, national and international policies to combat organ trade (commercialism) should conform the following:

All states should adopt legislative measures which would expressly prohibit making financial gain with human organs and advertising the need for or availability of organs with a view of offering or seeking financial gain. All states should support the UN and the Council of Europe efforts to adopt international convention that would define trafficking in organs for transplantation purposes and introduce criminal-law measures to fight against such practices.
Recommendation 6:  
Strengthen the responsibilities of health professionals towards the victims of organ trafficking, trade, or tourism (to organ providers)

International and national legislative frameworks emphasize the necessity of cooperation amongst various actors involved in the fight against organ trade and organ trafficking. While there are many issues that shall be handled with the help of other professionals and institutions (such as police, criminology, departments for fighting against organized crime, so on) the public health sector and the health care professionals have also their attributions in the fight against organ trafficking, organ trade and organ tourism. It is in the paramount interest of the health care professionals involved in transplantation that their day by day life saving efforts not to be shadowed by the phenomena of organ trafficking and organ trade. Therefore the international transplant community must deliver a concerted message that organ markets that exploit the poor and vulnerable are not acceptable.

One of the first international instruments on this field, the Council of Europe Recommendation no. 1611 of 2003 on Trafficking in Organs in Europe proposed the introduction of sanctions for the medical staff involved in transplanting organs obtained through illegal trafficking; the denial of national medical insurance reimbursements for illegal transplants abroad; the denial of national insurance payments for follow-up care of illicit transplants, except where such a refusal would endanger the life or health of patients unable to cover the cost of vital treatment themselves. The WMA and WHO Guidelines on human organ and tissue transplantation also address the issue of the professional obligation of physicians.

Based on the findings of our research we consider that in case of living donation the heath care professionals should assure the maximum safety for the donor. This includes, in line with international good practice, the need for follow-up in case of each living donor – results of the follow-up shall be communicated transparently by each transplant center and this should be monitored by the relevant authorities.

Adequate information should be provided to all living organ donors (and if applicable to their families) about the medical, health and legal impact of organ donation. Accurate medical records have a crucial role. Furthermore, the assessment of the nature of relationship between the donor and recipient should be made according to the relevant laws, but in case of doubt legal and psychological consultation should be conducted. In case of clandestine organ removal, victims shall be eligible for emergency and post-operative medical treatment. Furthermore, information should be provided to the victims on the accessibility of health care and legal aid independently to the legal (criminal sanctions) imposed on the intermediates and health professionals institutional ethics committees (in the lack of ethics committees) the head of the institution should be notified about the case to make necessary prevented steps.

The medical staff should be trained and be committed to comply with the relevant international ethical and legal standards. As it is almost impossible to prove whether instances of patients traveling abroad for organ transplants constitute ‘real’ cases of transplant tourism. The cross-border and complex nature of this act possibly makes it one of the most difficult crimes to prove and prosecute. This complexity raises challenges for doctors and other health care providers confronted with patients who opt for transplants abroad.

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81 Council of Europe Parliamentary Assembly Recommendation 1611 (2003) Trafficking in organs in Europe

82 WMA Statement on Human Organ Donation and Transplantation, Adopted by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 and revised by the 57th WMA General Assembly, Pilanesberg, South Africa, October 2006; WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, as endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22.
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Recommendation 7:
The need to strengthen the responsibilities of health care professionals in case of organ tourism (organ receivers)

Physicians should inform patients about the risks of the pre- and postoperative journey. Moreover, it would be recommended to identify patients at risk for organ tourism, information on risk and dangers, moral aspects, cooperation in preparing organ tourists. However, in case a patient returned already after organ tourism, physicians should provide postoperative care of returning organ tourists. Rules for re-admittance to the waiting list should cover such scenarios (if necessary). Transplant tourism shifts the traditional role of doctors as health care providers to “agents”, encouraged to deter and prevent transplant tourism. Below, we present recommendations for health care professionals confronted with patients who – presumably – bought organs for transplants abroad.

Recommendation 8:
Health care providers should dissuade patients from seeking organs abroad

Considering the medical complications that accompany transplants abroad, health care providers should dissuade the patient from going abroad by warning him/her against the medical risks. Contrary to what Gill et al. claim, doctors should refrain from informing or “educating” all patients about going abroad: this may bring the unintended consequence of putting ideas into the heads of patients who otherwise might not have considered the possibility at all. Such warnings should only be directed towards the individual patient who has expressed an interest or desire to undergo a transplant abroad.

While the international law is clear in its intention to prohibit all forms of organ trade, health care professionals often meet ambiguous cases when (suspected) organ tourists come for pre or post-operative treatment. Therefore we think it is essential to provide professional guidelines also for practitioners that help to translate international norms in context of the everyday life.

Recommendation 9:
States and professional associations should develop professional guidelines for professionals who may be in contact with organ tourists

Patients in general have a right to access their medical records and to receive a copy of it. Whereas the patient’s right to receive medical care remains untouched, it could be claimed that the doctor may consider disclosing patient information to the police. This consideration may arise in the situation where the patient outright declares to his doctor that he is going to buy an organ for transplant.

abroad from a trafficked or paid donor. Medical doctors should receive clear guidance (in the framework of their training) that they should not assist patients in buying organs, even if they would go abroad to do that. The collision of professional duties; respect the patients’ privacy on one hand and the duty not to commit and to assist crime, on the other hand should be eliminated by informing patients’ about the law and the health risks. Beyond these activities health care professionals should not promote or assist in any way the activity of buying organs by their patients.

**Recommendation 10:**
**Developing instruments for the prevention of organ trade and organ trafficking**

According to the international instruments on trafficking of human beings for the purpose of organ removal or organ trafficking prevention shall have a very important role in the fight against these negative phenomena. As it is stated in the reports on this phenomenon organ trade, trafficking and tourism are demand driven. One way of combating it is to increase the availability of legally procured organs and to keep the donation process in the framework of the legality. There are various ways to achieve this goal. Transferring best practices across countries is difficult because health policies are deeply embedded in country specific contexts and different actors in health care systems might have different ideas of what is “best”. Being aware of this fact, we propose that in a first step the volume of deceased donation shall be maximized. One measure towards this major goal can be the education of the healthcare professionals (and of the media), which is regarded as the most cost effective means of increasing the public’s willingness to donate. For increasing the rate of deceased donations special attention shall be provided for improving the knowledge of health professionals not directly involved in transplantation about transplantation issues. The Spanish Model of Organ Donation can be regarded as a possible model in this respect. One of the main elements of this model was the great effort in training programs targeted to all the professionals directly or indirectly involved in the process of donation. These training programs covered each step in the process of donation from donor detection and maintenance to legal aspects including brain death diagnosis, family approach, and organizational issues. In addition, trainings in areas such as management of resources or relation to the mass media have been also developed. While in some other European countries similar steps have been done already, there are still countries which should make more efforts in this direction.

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87 Council of Europe Convention on Action against Trafficking in Human Beings, Chapter II, Article 5; Article 6; Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the UN Convention on Organized Crime (2000), Art. 9.


Recommendation 11:
Empower Ethics Committees involved in Living Organ Donation decision-making

In the context of living organ donations the educational process could aim to improve the functioning of the committees involved in living organ decision-making in order to be more efficient in preventing the attempts of illegal activities that might occur in the transplantation process. Finally it would also involve raising awareness on the existence of the negative phenomenon of organ trafficking, trade and tourism, for making health care professionals alert to the detection of possible frauds.

By strengthening the role of Committees involved in living organ donation decision making process violations of the transplantation law could be minimized, the suspicions can be eliminated, and this can result in a better context in which living organ donation is carried out. At present the decision-making practice of such Committees is far from being unitary in translating the law into practice through purely objective criteria. While there are some shared principles that shall guide these Committees’ in decision-making, such as objectivity, impartiality, professionalism, transparency there exists a diversity in application and evaluation of principles in practice. The actual functioning of the committees are correlated with such contextual factors as: the institutional environment; the role of ethics in clinical decision making in that country/the transplantation unit; the experience and professional background of the committee members; the larger socio-economic and cultural context. The context therefore matters, however some organizational steps could be recommended cross-nationally for an enhanced transparency in living organ donation decision-making process.

It is desirable to provide the possibility of two alternate Committees in one hospital unit: the potential donor and recipient to be assessed by separate health care teams, if possible. When this is not possible a member of the Committee shall act as the “donors defender” whose responsibilities include but are not limited to the following: to promote the best interests of the potential living donor, advocate for the rights of the potential donor, assist the potential donor in obtaining and understanding information before the consent process, evaluation process, surgical procedure, and need for follow-up.

In order to ensure the diversity of Committee members’ backgrounds and affiliation it is recommended to bring non-transplantation unit members within, or rotating the membership of commissions among transplantation centers. The presence of a professional with specialization in medical ethics/bio-ethics is desirable.

The material/financial and structural/institutional conditions for the work of the Committees shall be provided. The decision-making process of the Committees should be transparent and accountable. Procedures to follow when donation does not proceed for various reasons (medical, donor’s change of mind) shall be established. External supervisory body overseeing the Committee’s work is necessary. More research should be done on the activity of the Committees for identifying barriers and strategies in implementing these structures.

Education, training and professional guidelines should be available for the members of the Committees. As the technology is changing it is necessary to conduct periodical reviews of the informed consent guidelines to verify that they contain up to date information about the conditions of the donation and its effects (including the latest results of research on the long term effects of donation, for example).

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Conclusion

European human rights and health law is unanimous in prohibiting all forms of organ trade and trafficking. Even beyond Europe, various supranational and transnational organizations have made efforts to reduce the occurrence of organ trade and trafficking by adopting international norms that call member states or states parties for prohibiting the commodification or commercialization of organ donation. Our research across a wide range of European countries have confirmed that while legal provisions repeatedly emphasize and reinforce the principles of non-commercialization, 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. There is also the added risk of developing illegal networks that clearly distinguish between organ supply and organ demand countries as well as institutionalize the exploitation that comes with this distinction. However, we have also identified good practices and promising efforts in regional co-operation that have contributed to the enhancement of the existing organ transplantation systems. Our chapter was a minor contribution to these positive developments with a special focus on the improvement of legislative and law enforcement mechanisms.

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Biographies

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Issues in organ replacement therapy represent a paradigm for ethics and questions of justice in modern medicine. The book—based on the December 2002 Munich International Congress on Ethics of Organ Transplantation—delivers an overview of current worldwide achievements, analyses, controversies, and dilemmas. It deals with the topics Equitable Allocation of Organs, Living Organ Donation around the World, Financial Incentives and Commerce in Organ Transplantation, Embryonic Stem Cell Biology / Cloning of Individuals, Genetic Engineering of Organs / Xeno transplantation, and Regenerative Medicine, which are intensely discussed among medical, ethical, and legal experts, and by the general public.

The question is raised: How to define the acceptable? And is there a single universal set of ethical norms the everyone worldwide could and should accept?

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Ethical, Legal, and Social Issues in Organ Transplantation
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W. Weimar, M.A. Bos, J.J. Busschbach (Eds.)

Organ Transplantation: Ethical, Legal and Psychosocial Aspects
Towards a Common European Policy

This book is based on the International Congress "Organ Transplantation: Ethical, Legal and Psychosocial Aspects. Towards a common European policy" (Rotterdam, The Netherlands, April 2007). The contributions deliver an overview of current worldwide achievements, analyses, controversies, and dilemmas. The topics:
- Commercialization and trafficking;
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- Altruism, counseling and psychological aspects of living donation;
- Minorities, religions, gender aspects;
- Expanded post mortem donor criteria, including Non Heart Beating donation;
- Role of patients, media and pharmaceutical industry;
are intensely discussed among ethicists, clinicians, psychologists, lawyers and policy makers in the field of organ transplantation.

The ELPAT platform is initiated with the aim to establish continuity in European communication on 'Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT)', after several ad hoc conferences had been organised in the last two decades. ELPAT is thus an attempt to facilitate and structure the European research area in this field of science. It is now an official body within the European Society for Organ Transplantation.

The project on ‘Living Organ Donation in Europe’ (EULOD) was a Coordination Action, funded by the Seventh Framework Programme of the European Commission from 2010-2012. It aimed to establish an inventory of living donation practices in Europe, explore and promote living donation as a way to increase organ availability, and develop tools that improve the quality and safety of living organ donations in Europe. The project had a broad European coverage with a specific focus on new EU Member States. Eleven institutions from ten European countries were involved. EULOD 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).
This book is based on the International Congress "Organ Transplantation: Ethical, Legal and Psychosocial Aspects. Expanding the European Platform" (Rotterdam, The Netherlands, April 2010).

The contributions are an overview of current issues in the field of transplantation ethics.

The topics:
- Organ Tourism and Paid Donation;
- Legal and Ethical Boundaries for Organ Transplantation;
- Diverse Populations;
- Deceased Donation;
- Psychological Care for Living Donors and Recipients;
- Samaritan / Unrelated Donation;

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432 pages, ISBN 978-3-89967-639-6, Price: 45,- Euro
Public campaigns in different European countries highlight an increasing awareness that public acceptance of organ donation is a crucial factor for the medical field of organ transplantation. However, addressing this complex matter requires a fresh perspective as to how governments truly engage with their public on issues which touch upon health care, morbidity, and mortality.

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All contributors are members of the European Platform ELPAT (Ethical, Legal and Psychosocial Aspects of Organ Transplantation).

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