

Introduction

Transplantation medicine is well developed and the best possibility to cure organ failure. However, too few donor organs are available¹ to entirely utilise the medical progress made in the field of organ transplantation.² This causes death every single day. In 2007, about ten people died in Europe every day due to the unavailability of donor organs³ and about 40,000 people waited for a donor organ.⁴ In 2010, even more people waited for a kidney or liver transplant, while less than 20,000 kidney transplantations and about 6,500 liver transplantations were performed during the same year.⁵ In Germany, right now about 12,000 people are listed as waiting for an organ transplantation.⁶

The rate of organ donation can be increased by making an effort to ensure that more organs are donated post-mortem or by increasing the rates of living organ donation (LOD).⁷ Even though opinion surveys show that the majority of the population is willing to donate organs after death, the actual donation rates are lower.⁸ Since it cannot be assumed that the waiting time for donor organs could be

¹ Abbub-Filho et al., in Gutmann et al. (ed.) (2004), p. 149; Broelsch, in Broelsch (ed.) (2006), p. 31; Coppen (2010), p. 9; Esser, in Höfling (ed.) (2003), p. 201; First, Vol. 29 Transplantation Proceedings 67, 67 (1997); Gutmann (2006), p. 4; Norba (2009), p. 55; cf. Oniscu/Forsythe, Vol. 38 Annals Academy of Medicine 365, 367 (2009); Ugowski (1998), p. 2.

² Beckmann, in Broelsch (ed.) (2006), p. 9; Deutsch/Spickhoff (2006), p. 433.

³ Pühler et al., Vol. 25 Medizinrecht 584, 585 (2007).

⁴ Commission of the European Communities (2007), p. 2; Pühler et al., Vol. 25 Medizinrecht 584, 585 (2007).

⁵ Matesanz (ed.), Council of Europe (2011); EULOD WP 2, Living Organ Donation Practices in Europe, p. 5.

⁶ Bundestag printed paper 17/9030 (2012), p. 3.

⁷ Gutmann/Schroth (2002), p. 1; Norba (2009), p. 24.

⁸ Cf. Bundestag printed paper 17/9030 (2012), p. 4; cf. Bundeszentrale für gesundheitliche Aufklärung (2010); cf. Hauptmann/O'Connor, Vol. 336 The New England Journal of Medicine 422, 425 (1997); cf. Kirste, Vol. 81 Der Chirurg 778, 778 (2010); cf. Morgan/Deedat/Kenten, in Weimar/Bos/Busschbach (ed.) (2008), p. 99 f.; cf. Robert Koch-Institut (2003), p. 23.

Table 1 Living kidney donation (LKD) pmp

Country	LKD in 1992	LKD in 1999	LKD in 2008	LKD in 2009
EU				
<i>Austria</i>	1.6	4.9		8.3
<i>Belgium/Luxemburg</i>	1.1	2.5	Belgium: 4.2	
<i>Bulgaria</i>		2.0	1.6	2.1
<i>Cyprus</i>		48.3	49.0	
<i>Czech Republic</i>		1.7	2.8	2.6
<i>Denmark</i>	8.6	7.8	13.5	16.3
<i>Estonia</i>		0.7	2.2	3.0
<i>Finland</i>	3.4	0.8	1.7	1.1
<i>France</i>	0.8	1.3	3.5	
<i>Germany</i>	1.2	4.6	6.9	7.3
	(West Germany)			
<i>Greece</i>	6.5	8.5	4.6	3.0
<i>Hungary</i>		0.9	2.4	2.4
<i>Italy</i>		1.4	2.2	2.3
<i>Latvia</i>			0.4	2.6
<i>Lithuania</i>		3.8	1.5	2.6
<i>Malta</i>			12.5	12.5
<i>Netherlands</i>	5.5	8.4	25.2	25.3
<i>Poland</i>		0.3	0.5	0.6
<i>Portugal</i>	0.0	0.9	4.7	6.0
<i>Romania</i>			5.3	5.1
<i>Slovakia</i>		0.4	3.6	
<i>Slovenia</i>				0.5
<i>Spain</i>	0.4	0.4	3.4	5.0
<i>Sweden</i>	10.3	11.8	14.8	17.7
<i>United Kingdom/Ireland</i>	1.6	4.3	UK: 15.3 Ireland: 1.2	UK: 16.0 Ireland: 0.0
Additionally				
<i>Moldova</i>			0.6	
<i>Norway</i>	17.1	18.5	20.5	21.6
<i>Switzerland</i>	3.8	9.0	15.3	13.0

sufficiently reduced by only using organs donated by deceased persons,⁹ LOD is a valuable supplement.¹⁰ LOD, hence, seems to be a useful and desirable option, making it a worthwhile focus of concentration.

The (increasing) importance of LOD can be confirmed by the fact that the amount of LODs has risen considerably since the beginning of the nineties in several countries. Table 1 shows the development of living kidney donation per

⁹ Cf. Ghods, Vol. 3 *Iranian Journal of Kidney Diseases* 183, 183 (2009); cf. Price (2010), p. 285.

¹⁰ Cf. Neft, Vol. 20 *Neue Zeitschrift für Sozialrecht* 566, 566 (2011).

million people (pmp) in the countries selected for this study.¹¹ The countries that show an increase in the amount of LOD since 1992 (or since the earliest year that the publication of numbers was provided for that particular country) are italicised.

LOD is rather common in most countries considered; it can even be considered an established standard therapy today.¹² It became clear, however, that the rates of LOD differ significantly between the countries, showing that not all countries actually tap the full potential.¹³ Not only does the medical development have an influence on the amount of LODs, the legal situation has an influence as well.¹⁴ Legal regulations, while not automatically increasing the amount of LOD, are one important factor among several in influencing LOD numbers. This will be analysed in detail by examining the arguments in favour of and against restricting LOD by law. Such analysis will confirm the statement of some legal experts that LOD regimes create in part an *artificial scarcity*.¹⁵

By presenting the national transplant laws in the countries considered, possibilities for LOD regulation will be demonstrated. This study will show the extent of similarities and differences in existing national laws. It can be assumed that some regulations are *better* than others. The final aim, therefore, is to figure out the best possible way to regulate LOD in order to make a contribution to solve the problem of organ shortage while adequately addressing the ethical, legal, and political side-constraints of the subject.

A legal comparison of the national transplant laws makes sense to find out which regulations would be best to address the issues of LOD in need of regulation. This is also in accord with the European Unions *Action plan on Organ Donation and Transplantation* which strives “to promote the exchange of best practices of living donation programmes (Priority Action 3).” A legal comparison is, furthermore, a first step to make a harmonisation of the regulations for LOD possible. Since the Member States of the European Union are continually growing more and more together, the field of organ transplantation is as well; such harmonisation is desirable.¹⁶

¹¹ The numbers for 1992 are from Jakobsen, in Price/Akveld (ed.) (1997), p. 5. The numbers for 1999 are from Matesanz/Miranda, in Gutmann/Schroth (2002), p. 256 f. The numbers for 2009 and 2010 are from Transplant Procurement Management (2011). The criterion for choosing the countries is connected to the object of investigation (Schnitzer (1961), p. 105; Zweigert/Kötz (1996), p. 40 ff), and the intent of the investigation can be an indication of the selection of the included legal systems (Constantinesco (1972), p. 51; Ebert (1978), p. 38). Since this thesis focuses on the European Union, logically all European Union-Member States are considered. Furthermore, Moldova, Norway and Switzerland are included.

¹² Price (2010), p. 196; cf. Wagner/Fateh-Moghadam, Vol. 56 *Soziale Welt* 73, 74 (2005).

¹³ Cf. EULOD WP 2 (2012), DOW: Deliverable 4, p. 4.

¹⁴ Gutmann/Schroth (2002), p. 42.

¹⁵ Cf. Evans, Vol. 15 *Journal of Medical Ethics* 17, 19 (1989); cf. Fateh-Moghadam, (2011); cf. Radcliffe Richards, in Weimar/Bos/Busschbach (ed.) (2011), p. 41.

¹⁶ Cf. Gutmann/Schroth (2002), p. 41; cf. Prechern-Hauptmann, in Höfling (ed.) (2008), p. 97.

Not only have the Member States of the European Union become active in the field of (living) organ donation, but the European Union has also already carried out several actions in this area. It even passed a binding directive in this field: *Directive 2010/53/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*. This *Directive* focusses on aspects of quality and safety of LOD (and post-mortem organ donation), but does not (completely) stipulate the requirements for LOD.

Does the European Union have the competence to regulate the requirements for LOD? This will be negated for hard law in chapter “Possibilities of Harmonisation”. However, the option to pass soft law remains. The European Union is definitely amenable for such non-legally binding tools, which was confirmed by the *White Paper on Governance*. The *White Paper on Governance* was published by the European Commission in 2001 and promoted using such soft methods.¹⁷ The option of the European Union to pass soft law to *regulate* the requirements for LOD, as being preferable towards no further measures, will thus be considered.

All in all, this thesis considers the national transplant laws, but also actions of the European Union that have already been done in this field and whether it has even further competences. The aim is to analyse the arguments in favour of and against legal restrictions of LOD to establish a best practice proposal in the end.

This thesis starts with an overview of LOD in chapter “Overview About Living Organ Donation”. The overview includes an introduction of LOD and defines the relevant terminology. Chapter “Comparative Analysis of European Transplant Laws Regarding Living Organ Donation” compares the national transplant laws from the countries considered. First, it explains the method the comparison of laws will follow, and then actually compares the issues of LOD in need of regulation. It especially focuses on how LOD is restricted in the countries considered. Chapter “Analysis of the Normative Arguments That Dominate the Policy Arena About Necessity and Legitimacy of Legal Restrictions in Living Donor Transplantation” analyses the normative arguments that dominate the policy arena about the necessity and legitimacy of legal restrictions in LOD. The arguments in favour of legal restrictions will be compared with those against such restrictions. LOD has not only been recognised by the national laws, but by the European Union as well, which is active in the field of LOD. The actions the European Union has carried out so far are therefore presented in chapter “Actions of the European Union So Far”. Whether the European Union has further possibilities to harmonise the legislation for LOD will be analysed in chapter “Possibilities of Harmonisation”. Chapter “Best Practise Proposal for Living Organ Donation in the European Union” will focus on the possible content of a unified regulation for LOD and establish a best practise proposal. In the end, a summary of the entire dissertation will be made.

¹⁷ Stefan, Vol. 14 European Law Journal 753, 760 (2008).

Regulations Regarding Living Organ Donation in Europe
Possibilities of Harmonisation

Lopp, L.

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