The Relevance of Directive 2010/53/EU for Living Organ Donation Practice: An ELPAT View

Kristof Van Assche,[1] Sigrid Sterckx,[1] Annette Lennerling,[2,3] Nizam Mamode,[4] Franco Citterio,[5] Mihaela Frunza,[6] Willij C. Zuidema,[7] Lisa Burnapp,[8,9] Willem Weimar,[7] and Frank J. M. F. Dor[10]

Abstract: With the recent transposition of *Directive 2010/53/EU* into the transplant regulation of EU Member States, the time is right to have a closer look at its implications for living organ donation practice. We first discuss the relevance of the *Action Plan* which forms the basis for the policy of the European Commission in the field of organ donation and transplantation. We then analyze the impact of *Directive 2010/53/EU* which was adopted to support the implementation of the Priority Actions set out in the *Action Plan*. We more specifically focus on the obligations of transplant centers engaged in living organ donation and highlight their significance for clinical practice. Finally, we point out some strengths and weaknesses of the *Directive* in addressing living organ donation.

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Organ donation and transplantation first entered the agenda of the European Union in 1997 with the adoption of the Treaty of Amsterdam.[1] In April 2007, the European Commission issued a *Communication on Organ Donation and Transplantation*, with the intention to respond to major challenges in the field of organ transplantation. It proposed a dual mechanism of action: an *Action Plan* aimed at enhancing cooperation between EU Member States and a binding legal instrument which would contain basic principles on the quality and safety of organs intended for transplantation.[2] Following this *Communication*, the European Commission issued its *Action Plan on Organ Donation and Transplantation (2009–2015)* in December 2008. It is running for a 6-year period and is scheduled to end in 2015. The aim of the *Action Plan* is to strengthen cooperation between EU Member States to increase the availability of organs, enhance the efficiency and accessibility of transplantation systems, and improve the quality and safety of organs.

The *Action Plan* identifies the promotion of living organ donation in EU Member States as one of the Priority Actions for increasing organ availability. It suggests a double strategy to increase living organ donation under conditions of safety. First, it proposes to exchange best practices on living organ donation between Member States. The final objective is to develop a toolbox which collects Member States' expertise and experiences in setting up living donation programmes and provides tools for the selection, evaluation, and protection of donors and for the collection of information on the consequences of living donation.[3]

Second, the *Action Plan* advocates the establishment of national registries of living organ donors to facilitate monitoring and follow-up. To this aim, the European Commission is cofunding a project intended to assist in the design and management of these registries and to set up a model for

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[1] *Department of Philosophy and Moral Sciences, Bioethics Institute Ghent, Ghent University, Ghent, Belgium.*

[2] *The Transplant Centre, Sahlgrenska University Hospital, Göteborg, Sweden.*

[3] *Institute of Health and Care Sciences, The Sahlgrenska Academy at the University of Gothenburg, Göteborg, Sweden.*

[4] *Department of Transplantation, Guy's Hospital, London, United Kingdom.*

[5] *Department of Surgery, Catholic University, Rome, Italy.*

[6] *Department of Philosophy, Babes-Bolyai University, Cluj, Romania; The Academic Society for the Research of Religions and Ideologies, Cluj, Romania.*

[7] *Department of Internal Medicine, Nephrology and Transplantation, Erasmus MC, Rotterdam, the Netherlands.*

[8] *Lead Nurse, Living Donation, NHS Blood and Transplant, London, United Kingdom.*

[9] *Living Donor Kidney Transplantation, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom.*

[10] *Division of Transplant Surgery, Department of Surgery, Erasmus MC, Rotterdam, the Netherlands.*

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Correspondence: Kristof Van Assche, PhD, LLD, Bioethics Institute Ghent (BIG), room 120, Ghent University Blandijnberg 2 BE-9000 Ghent, Belgium. (Kristof.VanAssche@UGent.be)

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supranational data sharing, resulting in a European living donor "Registry of Registries."[4] It is assumed that the information to be compiled with the aid of these systems will contribute to the improvement of living donor care in the European Union and to the harmonization of existing regulations in the field.

In July 2010, *Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation* was adopted to support the implementation of the *Action Plan*. The *Directive* requires EU Member States to adopt minimum standards with regard to key aspects of organ donation and transplantation. In addition, every Member State has to designate a competent authority—as a rule, this task is assumed by the appropriate national transplant organization—responsible for establishing a national framework for quality and safety of organs and for implementing the *Directive*. The main purpose is to improve the quality and safety of organs intended for transplantation, which should lead to better screening, a better match, reduced risks for recipients and living donors, and less organ failure.

As a result of these regulatory and organizational measures, the *Directive* will have a profound harmonizing effect on transplant practice in the 28 Member States of the European Union. Moreover because many other European countries (e.g., countries candidate to accession to the European Union and countries involved in international organ exchange with EU Member States) are in the process of aligning their transplant regulation with EU policy, the impact of the *Directive* extends far beyond EU borders. Its provisions had to be transposed in the domestic law of EU Member States by 27 August 2012.[5] Notwithstanding this strict deadline, several EU Member States have only very recently finalised the transposition process. Therefore, now is the right time to analyse the relevance of the *Directive* for living organ donation practice.

To this end, the Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) section of the European Society for Organ instituted a working group on this topic. The ELPAT is a European platform that brings together professionals, such as transplant surgeons, transplant coordinators, specialist nurses, (bio-)ethicists, lawyers, psychologists, physicians, sociologists, anthropologists, policy makers, and criminologists, to debate and stimulate research on the issues surrounding transplantation. This article contains the findings of the ELPAT working group on the estimated impact, strengths and weaknesses of *Directive 2010/53/EU*.

OBLIGATIONS UNDER *DIRECTIVE 2010/53/EU* AND THEIR ESTIMATED IMPACT

In what follows, we will briefly highlight the provisions which impose specific obligations on transplant centers and health care professionals engaged in living organ donation. An overview of these obligations is presented in Table 1. At the same time, we will assess the estimated impact of these obligations on clinical practice. An overview of the clinical practice at the time of the implementation of the *Directive* is presented in Table 2.

Medical Assessment of Prospective Living Donors and Minimization of Risks

The *Directive* requires prospective living donors to undergo a thorough medical screening to determine possible health risks for donor and recipient and the suitability of the organ for transplantation. This assessment should be performed by qualified health care professionals on the basis of the prospective donor's medical history, an interview, and a physical examination and complementary tests.

In addition, the *Directive* requires that the highest possible protection of living donors should be ensured. As a result, living organ donation should not be allowed if this would present unreasonable medical risks and the procurement itself should be performed in a manner that minimises the risk to the donor.

Data from transplant centers indicate that these are general principles that are already well established and universally applied. Differences in practice between transplant centers concern more technical aspects, such as accepting certain medical conditions as a contraindication for living donation and the possible additional requirement of psychosocial screening of prospective donors. Although similar absolute contraindications for donation are reported in all countries, it should be noted that no precise regulations on donor screening exist at international level and that there is a certain lack of evidence regarding most of the (relative) contraindications for living kidney donation, as reflected in the relevant guidelines.[7] Because of the general nature of its provisions on medical assessment and risk minimization, the *Directive* will not have much added value in this respect.

TABLE 1.
Obligations of transplant centers under *Directive 2010/53/EU*

Medical assessment of prospective living donors	Article 7 Preamble, para 12
Minimization of risks to prospective living donors	Article 15, paras 1 & 2
Obtaining valid consent or authorization	Article 14 Preamble, para 23
Maintaining confidentiality and anonymity	Article 16 Preamble, para 22
Providing adequate follow-up of living donors	Article 15, para 4
Collecting data on living donation	Article 15, paras 3 & 4 Article 18, para 1
Identifying, reporting and managing unintended and unexpected situations	Article 11
Transmitting data allowing traceability of organs	Article 10

Obtaining Valid Consent or Authorization

The *Directive* states that the procurement of an organ from a living person is only allowed after all requirements relating to consent or authorization, in force in the Member State concerned, have been met. It is specified that consent or authorization should be explicit, free and based on information about, at least, the purpose and nature of the donation and its consequences and risks.

These provisions do not go beyond what is recommended by international ethical guidelines and legal instruments. Moreover, data from transplant centers indicate that the need to obtain valid consent or authorization is a long-standing, essential rule of transplant practice. Differences in practice concern the modalities of the consent (e.g., written or verbal) and the extent of the information to be provided. Since the

TABLE 2.

The 28 EU member states divided into geographical regions

	LKD performed	<25 LKD performed/ year	Unspecified donation accepted	Psychosocial screening required	Hypertension >140/90 no contra-indication	Written consent required	Donor follow-up		Donor registry		Reporting/management serious adverse events/reactions	Organ traceability
							offered	life-long	in place	national level		
Northwestern Europe		45%	50%	58%	6%	68%	100%	48%	97%	40%	No precise data available	No precise data available
Austria	Y											
Belgium	Y											
Denmark	Y											
Finland	Y											
Germany	Y											
Ireland	Y											
Luxembourg	N											
Netherlands	Y											
Sweden	Y											
United Kingdom	Y											
Mediterranean		73%	20%	63%	6%	94%	100%	50%	93%	34%		
Cyprus	Y											
Croatia	Y											
France	Y											
Greece	N[a]											
Italy	Y											
Malta	Y											
Portugal	Y											
Spain	Y											
Eastern Europe		81%	3%	63%	16%	80%	40%	30%	81%	41%		
Bulgaria	Y											
Czech Republic	Y											
Estonia	Y											
Hungary	Y											
Latvia	Y											
Lithuania	Y											
Poland	Y											
Romania	Y											
Slovakia	Y											
Slovenia	N											

Data received from an online survey from 2011 to 2012 of living kidney donation (LKD) centers in Europe[6]

[a] Greece did not have a LKD-programme in place in 2011 due to the financial crisis.

Directive contains no precise provisions in this regard, it will not require a change of practice.

However, confronted with the requirement to implement the *Directive*, several EU Member States still seem to have taken the opportunity to strengthen their information and consent regulations. For instance, in Belgium and Luxembourg, the fulfilment of consent requirements will henceforth need to be assessed by a pluridisciplinary team and in France and Greece the range of information to be provided to prospective living donors is broadened.

Maintaining Confidentiality and Anonymity

The *Directive* requires that strict confidentiality rules and security measures are put in place for the protection of the personal data of donors and recipients. It is clarified that, in cases of unspecified living donation (i.e. where the living donor and the recipient do not know each other) and specified indirect donation (i.e. when a willing but incompatible person donates to an unknown recipient within an exchange or sharing scheme, or for a higher position on the waiting list for his or her intended recipient), transplant teams should not disclose the identity of the recipient to the donor and vice versa.[8]

However, the requirement of maintaining anonymity may be waived under 2 conditions. First, when there is a medical need to make such information available to donors or recipients (e.g., in the case of transmission of a communicable disease). Second, when revocation of anonymity is allowed under domestic law and both the donor and the recipient have given their explicit consent. In practice, revocation of anonymity before transplantation is not allowed in any EU Member State and revocation of anonymity after transplantation currently seems only allowed in the United Kingdom, subject to the mutual consent of both parties.[9]

With regard to confidentiality and anonymity, the *Directive* is only reiterating general principles that have been put forward by binding international data protection instruments.[10] Since these principles have already been applied to the transplant setting by all EU Member States, the estimated impact of the *Directive* on current data protection practice will remain very limited.

Follow-up of Living Donors

The *Directive* requires that one should consider providing living donors with adequate follow-up. Data from transplant centers indicate that donor follow-up is currently already being offered in all living kidney donation centers in Northwestern and Mediterranean Europe. In almost half of these centers, follow-up is even life-long. In contrast, only 40% of Eastern European centers currently offer follow-up to living donors, and this follow-up is very frequently limited in time.

Regulations across EU Member States vary widely, not only with regard to the need to offer follow-up, but also with regard to its modalities (e.g., intervals of the medical check-ups, individualization of the aftercare plan, need to alert donors to the importance of follow-up). Although the *Directive* stresses the crucial importance of offering follow-up to living donors in those EU regions where this is currently absent, its impact will likely be rather limited. The main reason is that, in contrast to the other obligations set forth in the *Directive*, the provisions on donor follow-up are not binding. Moreover, the *Directive* does not contain more specific requirements that would prompt EU Member States to reconsider the modalities of their domestic regulations of donor follow-up.

Collecting Data on Living Donation

The main organizational innovation of the *Directive* involves the establishment at the level of each Member State of central registries, maintained and administered by the national competent authority. One of these registries is the national living donor registry, which compiles data directly related to living organ donation. Data from transplant centers indicate that donor registries are already in place in almost all living kidney donation centers in Northwestern and Mediterranean Europe and in more than 80% of Eastern European centers. However, most of these registries are administered by the transplant centers themselves, with living donor registries at national level very frequently not yet operational.[11]

National living donor registries will have to collect 2 types of data, which transplant centers are required to systematically provide. The first type of data concerns aggregated numbers of living donors and the types and quantities of organs procured and transplanted, or otherwise disposed of. On the basis of these data, the national competent authority has to draw up an annual report and make it publicly accessible. The second type relates to relevant post-transplantation data. During follow-up of living donors and the recipients of their organs, transplant centers are required to collect and to report all data relevant for the quality and safety of the transplanted organs. These data will mainly focus on mortality and morbidity but may include a variety of additional data. What data will need to be compiled and transmitted will depend on the guidance issued by the national competent authority.

By requiring that certain types of data should be collected and then centralised at national level, the *Directive* will in many EU Member States result in a major shift in practice. Moreover, with plans being developed at European level to harmonise national living donor registries and to establish an overarching European living donor registry, centralization of relevant data will further increase. In this way, transplant centers and policy makers will have access to an enormous amount of information that may greatly contribute to the improvement of living donor care.

Identifying, Reporting, and Managing Unintended and Unexpected Situations

In addition to collecting data on living donation, the *Directive* also requires transplant centers to establish operating procedures for the identification, reporting and management of so-called serious adverse events and serious adverse reactions occurring at any stage of the chain from living organ donation to transplantation of the organ. Serious adverse events are undesired and unexpected occurrences that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for the living donor or the recipient of the organ, or which result in, or prolong, hospitalization or morbidity. Similarly, serious adverse reactions are unintended responses, including a communicable disease, in the living donor or the recipient, that

are fatal or life-threatening, disabling or incapacitating, or which result in, or prolong, hospitalization or morbidity.

Serious adverse reactions may manifest themselves after the persons concerned have been discharged from hospital and as such will constitute relevant post-transplantation data that will already need to be included in the national living donor registry. Notwithstanding this possibility, important information concerning serious adverse events and reactions needs to be transmitted to a central reporting and management system put in place by the competent authority. This system should allow timely notification of any serious adverse event and reaction to the competent authority and to other transplant centers concerned. In turn, this should trigger operating procedures aimed at managing risks and improving safety measures.

No precise data are available on the extent to which EU Member States have already put in place operating procedures for the identification, reporting and management of serious adverse events and reactions. However, the practice in EU countries where living donation is frequently performed (e.g., The Netherlands, Sweden and UK) indicates that no official central registration of serious adverse events and reactions existed prior to the adoption of the *Directive*. However, following the implementation of the *Directive*, such a central registry is now being established by national competent authorities, with transplant centers obliged both to communicate serious adverse events and reactions as they occur and to issue an annual report. It is clear that by introducing this kind of obligation, the *Directive* entails a major change of practice in EU transplant centers.

Transmitting Data Allowing Traceability of Organs

Apart from a living donor registry and a reporting and management system for serious adverse events and reactions, the national competent authority is also required to establish and maintain a central system for organ traceability. This system should ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa. Traceability allows the alarm to be raised if serious adverse events or reactions occur and is therefore crucial for the protection of vital interests of the individuals concerned.

The data need to be stored for a minimum of 30 years and have to be systematically provided by transplant centers. The data concerned include the characterization of the organ, the identity of the living donor and the recipient, the transplant centers involved and all relevant information relating to products and materials coming into contact with the organ.

Although no exact data are available, systems of organ traceability seem to have been established long before the adoption of the *Directive*. With, for instance, well-functioning traceability mechanisms in place at the level of international organ exchange organizations such as Eurotransplant and Scandiatransplant, albeit currently not directly dealing with living donation, the relevance of the *Directive* in this respect will be rather limited.

STRENGTHS OF THE *DIRECTIVE*

The crucial importance of the *Directive* lies in the requirement of establishing, at the national level of each EU Member State, a very extensive regulatory framework aimed at protecting living donors and monitoring and improving the quality and safety of organs (Table 3). When compared to current practice, the added value is 3-fold.

The *Directive* encourages transplant centers to systematically offer donor follow-up where this is not yet provided. This is mainly relevant for Eastern European transplant centers but it may also prompt many transplant centers in Northwestern and Mediterranean Europe to reconsider their follow-up policy so that it is no longer limited in time.

In addition, the *Directive* requires living donor registries, which before frequently were only administered by the individual transplant centers, to be centralized at national level. By establishing a national living donor registry, which will be connected to the living donor registries of the other EU Member States, it will be possible to more accurately monitor the extent, long-term outcome and other characteristics of living organ donation in the EU. Similarly, by centralising an enormous amount and a greater variety of relevant post-transplantation data, insights into living donor care may be significantly improved.

Furthermore, the *Directive* will result in the implementation of operating procedures for the identification, reporting and management of serious adverse events and reactions, with a central registry to be established at national level. This will likely lead to better risk assessment and perfecting of safety measures.

Apart from these aspects, the significance of the *Directive* lies in its binding nature. Several of the obligations set forth in the *Directive* were previously only recommended by international ethical guidelines but are now explicitly imposed. In doing so, the *Directive* will also have a profound harmonising effect on living organ donation practice in the EU.

In sum, it is to be expected that the *Directive* will succeed in its goal: improving the quality and safety of organs intended for transplantation, resulting in better screening, a better match, reduced risks for donors and recipients, and less organ failure.

WEAKNESSES OF THE *DIRECTIVE*

Although the EU *Directive 2010/53/EU* has to be applauded as a crucial instrument, some of the practical implications of the implementation of its provisions remain unaddressed. The main concerns relate to the major investments that are required to successfully deploy the quality and safety framework. The costs of establishing a tightly regulated national transplantation system, responsible for the supervision of transplant activities, the accreditation and control of transplantation centers and the maintenance of 3 distinct national registries, may prove difficult to shoulder for several EU Member States.

Similarly, at the level of the transplant centers and individual health care professionals, the procedures related to audits, training programmes, follow-up and accurate collection and reporting of information, may significantly add to the workload. In the face of increasing pressure to reduce expenditure in health care and in hospitals, the implementation of these requirements of the *Directive* may prove a real challenge to some centers.

In addition, in contrast to the level of detail of many of the more technical provisions, several of the provisions aimed at protecting living organ donors are very general. With the exception of registration requirements, these provisions frequently do not go beyond or even stay well below what

TABLE 3.

Summary of strengths, estimated impact and weaknesses of *Directive 2010/53/EU*

Strengths		
	Establishment of extensive regulatory framework aimed at monitoring and improving quality and safety of organs, and protecting living donors.	
	Binding nature of obligations that previously were only recommended by international ethical guidelines.	
	Harmonization of living organ donation practices in EU.	
Estimated impact		
	No change in practice concerning medical assessment of prospective donors, minimization of risks to donor, obtaining valid consent or authorization, and maintaining confidentiality and anonymity.	already well-established and revised regularly
	More emphasis on need to provide donor follow-up where this is not yet in place (especially Eastern Europe).	
	Establishment at national level of 3 central registries:	
	Living donor registries already established in nearly all transplant centers but frequently not yet centralised.	
	System for organ traceability already established, centralised and operational in most EU Member States.	
	System for reporting and management of serious adverse events and reactions not been established in most EU Member States.	
	Need to become familiar with meaning and implications of new concepts introduced by *Directive*.	
	New duties arising as a result of audits by competent authorities, need for periodic training, and commitment to provide follow-up of living donors.	
Weaknesses		
	Major investments required at national level to successfully deploy quality and safety framework.	
	Increased workload at level of transplant centers and individual health care professionals.	
	General nature of provisions aimed at protecting organ donors (especially with regard to valid consent/authorization).	
	No requirement of guaranteed follow-up (even in absence of proper private insurance coverage), guaranteed coverage of expenses and loss of income for living donors, guaranteed compensation in event of disability or death of donor because of complications, and guaranteed transplantation in case living donors become renal insufficient.	
	Lack of supervision and harmonization of sanctions that apply in case of noncompliance.	

is recommended by international ethical guidelines and legal instruments.[12] For instance, compared to the recommendations issued in the *Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor*, the *Directive* does not require psychosocial evaluation of prospective donors and long-time follow-up of living donors.[13] More problematically, with regard to the requirements for valid consent of a living donor, the *Directive* only refers to domestic regulations. Although this approach may be partially explained by the restricted scope of the *Directive*, we regret the fact that the *Directive* has not even laid out minimal standards that need to be met in order for the consent of a living donor to be valid and that the opportunity was not taken to harmonise consent procedures across EU Member States.[14]

Moreover, the *Directive* only requires Member States to endeavor to carry out the follow-up of living donors, whereas this requirement is an obligation under most of the aforementioned international ethical guidelines and legal instruments. Considering that in many European countries follow-up is covered by the insurance of either the recipient or the donor, it would have been a major step forward if the *Directive* would in addition have required guaranteed and life-long follow-up even in the absence of proper private insurance coverage.

Similarly, the protection of living donors would have been greatly enhanced if the *Directive* had required guaranteed coverage of expenses and loss of income for living donors, guaranteed compensation in the event of disability or death of the donor because of complications, and guaranteed transplantation in case living donors become renal insufficient. Various further proposals have been made in recent times, aiming to provide nonmonetary rewards to living donors, for example, the proposal by the Dutch Health Council that in case a living kidney donor becomes in need of a kidney transplant, he/she should be put on top of the waiting list for a deceased donor kidney.[15]

Finally, the *Directive* remains very vague with respect to the sanctions that apply in case of noncompliance. While transposing the provisions of the *Directive* into their domestic law, EU Member States are required to lay down rules on the applicable penalties and to ensure that these penalties are implemented. However, the *Directive* merely indicates that these penalties should be effective, proportionate and dissuasive. Although it is provided that EU Member States should notify the European Commission of the measures taken, the lack of supervision and harmonization of sanctions may be a cause for concern.

CONCLUSIONS

Directive 2010/53/EU is a very important legal instrument with major implications for living organ donation practice. We have identified 8 obligations to be addressed by transplant centers engaged in living organ donation. Several of these obligations reiterate in a general way what is already recommended by international ethical guidelines and other legal instruments. In this respect, the added value of the *Directive* lies in its binding nature and harmonizing effects on living organ donation practice.

The main significance of the *Directive*, when compared to other international legal instruments, is situated in its requirement to establish at the national level of each Member State 3 central registries aimed at monitoring and improving the quality and safety of organs. As these registries are gradually being deployed, transplant centers will need to systematically report a wide variety of data on living organ donation. These and other obligations faced by health care professionals may result in major changes in practice.

In addition, authorities and health care professionals will need to become familiar with the meaning and implications of the new concepts introduced by the *Directive* (e.g., serious adverse events and reactions, traceability, donor characterization, confidentiality of data). Furthermore, new duties may arise as a result of regular audits to be performed by competent authorities, the need for periodic training and the commitment to adequately organise and provide follow-up of living donors.

The weaknesses of the *Directive* are related to the significant costs and efforts required for the implementation of its provisions and to its failure to elaborate more detailed standards and procedural safeguards aimed at enhancing the protection of living donors.

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