

# Regulatory bases of living-donor transplantation

José Luis López del Moral

Senior Judge. Chairman of the Regional Court of Appeal of Cantabria. Spain

Nefrologia 2010;30(Suppl. 2):23-9

doi:10.3265/Nefrologia.pre2010.Nov.10688

## ABSTRACT

Living donor kidney transplantation is regulated in Spain by the transplantation law 30/1979 and developed by Royal Decree 2070/1999. These policies permit the living donation of an organ while its function is compensated by the rest of the body. It further specifies that the destination of the organ must be the transplantation in a specific person (this specification allows for the donation, not only among emotionally related, but between people that do not know each other, provided it is done altruistically, without any purpose of profit and without coercion).

The donor must be competent, healthy and had reached 18 years old (which is evidenced by a medical certificate) and should be well informed of the consequences of their decision.

The donor must give their consent to donation, free from inducement and consciously in the courts of civil registration.

In order to guarantee the quality and safety of the procedure, the centers that performed this therapeutic must be authorized both for the nephrectomy and the transplantation.

## INTRODUCTION

Thirty years have passed since the Spanish Law 30/79 was published on organ removal and transplantation. At present, it is a valid and efficient tool used to regulate this issue, and ensures that the system is highly reliable. Ethical and legal issues associated with living-organ donation are inevitable, as the situation involves performing a medical procedure on

## Bases legales de la donación de vivo

### RESUMEN

*El trasplante renal de donante vivo está regulado en España por la Ley de Trasplantes 30/1979 y desarrollada mediante el Real Decreto 2070/1999. Nuestra ley permite la donación en vida de un órgano si es compatible con la vida y la función del órgano o parte de él compensada por el organismo. Específica, además, que el destino del órgano será su trasplante a una persona determinada sin que medie condicionamiento económico, psicológico ni social (esta especificación permite la donación no sólo entre personas emocionalmente relacionadas sino también entre desconocidos, siempre que se realice de forma altruista y desinteresada).*

*El donante ha de ser mayor de edad, con plenas facultades mentales y un adecuado estado de salud (que se acredita mediante certificado médico) y deberá ser plenamente informado de las consecuencias de su decisión.*

*El donante debe otorgar su consentimiento de forma expresa, libre y consciente ante el juez del Registro Civil.*

*Los centros que realizan el trasplante renal de donante vivo deben estar autorizados tanto para la extracción como para el trasplante de dicho órgano de donante fallecido (para garantizar la calidad y seguridad del procedimiento).*

a healthy person, not to improve his or her own health or quality of life, but that of someone who is ill.

The Law defines a model established upon principles which provide legal security, and ensures that this process is based on ethical foundations and that the donor's fundamental rights are respected. The main socially-accepted foundations of a transplantation model are: non-remunerated donation, only for therapeutic purposes, confidentiality, limiting the promotion and advertisement of donation, and equity in possible recipient selection and access. New techniques that have already been tested in other countries should be introduced into the Spanish model, given the system

---

**Correspondence:** José Luis López del Moral  
Magistrado.  
Presidente de la Audiencia Provincial de Cantabria. Spain.  
jl.lopezdelmoral@justicia.mju.es  
Lopez\_j@uscantabria.es

reliability and that we are constantly striving to shorten the waiting list and improve the imbalance between those waiting for a transplant and those who receive one. These new techniques include crossover kidney donation and altruistic donation, both of which could be accepted by existing legislation.

The living donor's consent can only be considered valid if it has been provided after receiving detailed information about all the consequences and repercussions that could come of his or her decision, which should always be made considering the benefits expected for the recipient.

Consent must be given before a civil registry judge, and in order to be considered valid, the donor must be at least 18 and be mentally competent. Nephrectomy should not be carried out if it is suspected that the donation has been made due to financial problems or other type of coercion.

## 1. BASIC REGULATION: SPANISH LAW OF 27 DECEMBER ON ORGAN REMOVAL AND TRANSPLANTATION

### I. General principles

Law 30/79 outlines the basic regulatory framework as regards human organ donation, removal, preservation, exchange and transplantation. All of these activities must only be carried out for therapeutic purposes (Article 1), notwithstanding any additional research that can be conducted.

Despite the Law being developed on only seven points, they define the general ruling of this issue and make reference to the relevant regulation for each specific activity.

A general principle established is that donation must be free, expressly prohibiting the donor to receive remuneration for donating his or her organs. Nor is the recipient allowed to demand a given price for the donation. Notwithstanding the above, and with the aim of not hindering the donation

process, those intervening in the process must apply the necessary measures to ensure that the donation would not financially burden the donor in any way.

## II. Legal ruling for living donation

There is a difference in the regulation depending on whether the donor is living or deceased. For the purpose of this article, we are only interested in the former, living donation.<sup>1</sup>

The Law requires the following **conditions** for living donation, which ensure that the donor's consent is valid (Article 4) :

- a) **The donor is of legal age.** The age referred to by the Law is 18, meaning that those over 16 years, although competent to make other types of healthcare decisions, are not permitted to be donors.<sup>2</sup> Legal age required by this legislation is that foreseen by Article 12 of the Spanish Constitution (18 years).
- b) The donor **is mentally competent.** People that suffer from a mental deficiency or illness, or that for any other reason are not able to validly give consent, are not able to donate organs.
- c) The donor have **been previously informed**<sup>3</sup> of the consequences of this decision (concerning physical, mental and psychological aspects), as well as the possible repercussions that the donation may have on his or her personal, family and professional life.

The donor will also be informed of the benefits expected for the recipient.

Sometimes we must question whether the patient's right to not be informed<sup>4</sup> may be applied in organ removal cases, provided that the patient has expressly refused to be informed. However, in any case, the patient must still always give consent to the medical procedure in question. In fact, there are restrictions as to when a

---

1. A living donor is someone who, in compliance with the requirements established under article 9 of the Spanish Royal Decree 2070, donates an organ(s) or part of an organ(s), which should only be removed if the donor's life is not at risk and its function can be adequately and safely compensated by the rest of the donor's body.

2. Article 9 of the Spanish Law 41/2002 of 14 November regulates the patient's independence and the rights and obligations with regards information and clinical documentation.

3. The Spanish Supreme Court of Justice stated in this respect that the information provided to the patient must be clear and detailed so that he or she is able to decide whether or not to subject him or herself to the medical procedure that the doctor has proposed. The Order of 17 October 2000 states that the information is intended to help the patient so that he or she can freely chose among the possible options, including not undergoing any therapy or intervention.

4. Article 9.1, Spanish Law 41/2002.

patient can exercise this right, i.e. when it may endanger the patient's own health, that of a third party or the community, or when therapeutic requirements demand so. As such, given that the donor is a healthy person undergoing an intervention which is not indicated for his or her own health but to improve someone else's, it therefore seems that the right to information must be mandatory. The right that a potential living donor has to reject information is questionable, given that he or she is a person that does not need any therapeutic intervention, and therefore, the donor must state that is aware of the risks associated with the intervention and the foreseeable advantages expected for the recipient. The information content provided to the donor (according to the terms given in the same law) indicates that it is similar to that for "voluntary and self-satisfying medicine".<sup>5</sup> The only information regarding risks that may be excluded would be adverse effects that may still not be known by medical science.

**d) The donor has expressly, freely and consciously given consent.<sup>6</sup>**

The Law finally demands that the consent is expressed before the duly specified public authority (the civil registry judge, as the implementing regulation specifies). Consent must be provided once the doctor who is to remove the organ has explained the intervention to the donor, which will also sign the organ donation consent.

**e) The removed organ is transplanted into a specific person, with the aim of substantially improving their expected survival or quality of life.<sup>7</sup>**

This requirement must be interpreted in accordance with the principles given in the Law, especially, the therapeutic objective of the organ transplantation. As such, donation is permitted if the organ is transplanted

into a specific person, who may or may not be identified from the beginning (or may be identified by a registration number), as the objective is to improve the health and quality of life of that person who will be finally identified. The legal text would also permit donation to an unidentified recipient on a transplant waiting list, who is later identified from those registered on the list. The Law only intends that the donated organ is to be used for a person, and that the only purpose of the donation is to improve the recipient's health or quality of life. Any type of identification procedure is also permitted by these requirements, provided that it allows for a living organ donation and that the organ is to be implanted in a recipient for whom the therapeutic activity is indicated.

**f) The recipient's anonymity is ensured.** This requirement reflects that the Law supports the principle of confidentiality, one of the principles governing the whole donation and transplantation process. This is also reiterated in Article 7 of the Spanish Law 41/2002 on patient independence. Living organ donation practice shows that this requirement must be met when a live donation is to be made to a specific person that has not been identified by the donor, as has been noted above.

### III. Recipient's informed consent

Lastly, Article 6 of the Law states certain requirements that must concur so that the doctor responsible for the transplant is able to give his or her approval for the intervention. The requirements must be considered with the recipient in mind,<sup>8</sup> a patient whose rights are completely recognised by Law 41/2002:

**a) The recipient is fully aware of the type of intervention that he or she is to undergo, and fully understands the risks and expected benefits associated with it.**

5. The Supreme Court of Justice has decided that more detailed information should be given. Therefore, the Order of 21 October 2005, on an aesthetic or reparative surgery case, states that the patient should be notified of any after-effects, risks, complications and adverse effects, independently of their frequency and that the intervention is performed without any technical error. The patient must also be informed of the possibility of these events even though they may be remote, not very likely or exceptional.

6. Informed consent is one of the latest contributions made by the Supreme Court to the Human Rights theory. It was declared in Room 1 (for civil issues) that it constitutes an essential human right and is a necessary consequence of traditional rights to life, physical integrity, and freedom of conscience, as well as the right to personal freedom, to decide upon situations concerning yourself, your life, and the use of your own body.

7. Royal Decree 2070 defines organ transplantation as the therapeutic use of human organs which consists in replacing an unwell organ, or organ which does not function correctly, with another from a living or deceased donor.

8. Recipient: is a person who receives the transplantation of an organ for therapeutic purposes.

- b) The recipient has been **informed** that the relevant donor-recipient compatibility tests have been conducted.
- c) **The recipient expresses his or her consent** to perform the transplantation **in writing**. If the recipient is not of legal age (16 years old) or competent, consent would have to be given by a parent, tutor or guardian. This right to information is susceptible to being renounced, in the terms foreseen by the Spanish Law on Patient Independence.

## 2. IMPLEMENTING REGULATION. SPANISH ROYAL DECREE 2070/1999 OF 30 DECEMBER WHICH REGULATES PROCUREMENT AND CLINICAL USE OF HUMAN ORGANS AND REGIONAL COORDINATION OF ORGAN AND TISSUE DONATION AND TRANSPLANTATION

### I. Basis and background

This regulation replaces the Spanish Royal Decree of 22 February 1980, developing the Law 30/79, and which was in force for almost 20 years.

Royal Decree 2070/99 was promulgated due to scientific and technical advances in diagnosing brain death, organ preservation and transplantation. With regards living donation, the Law specifies requirements that must be met to strengthen the validity and spontaneity of the donor's consent. It also establishes certain ethical principles on which this type of donation is based.

### II. Scope

The Royal Decree is applied to the procurement and clinical use of human organs, including donation, removal, preparation, transportation, distribution, transplantation and further process follow-up. This Royal Decree also regulates organ and tissue coordination between Spanish regions.

The legal mandate reiterates that the purpose of these activities must be therapeutic, i.e. that they must only be performed to benefit the recipient's health or quality of life, and always respect the recommended ethical principles of biomedical research and fundamental human rights.

### III. Fundamental principles

Current regulation (based on the Laws 30/79, 41/2002 on Patient independence and Organic Law 15/99 on Personal Data Protection) is founded upon the following principles:

**Confidentiality**<sup>9</sup>: This principle does not allow information regarding donor or recipient identification to be provided or circulated. This is also the case for the donor or recipient family members and applies to the circulation of any other type of information that may relate both people.

The manner in which these data are collected, stored and treated must respect confidentiality and restricted access criteria included in the Law on Personal Data Protection and in the General Law on the Health and Patient Independence. The person responsible for the documentation will adopt technical and organisational data security measures ensuring that they can not be modified, lost, treated or accessed by unauthorised parties. This person, and any other person involved in data treatment, is obliged to keep all information a professional secret, even once their professional relationship has ended. This principle does not however prohibit preventative measures from being adopted if it is believed that an individual's or community health is at risk.

**Promotion and advertising restrictions**: Organ donation must be promoted in a general manner, indicating the altruistic and voluntary nature of the process. It must not be advertised on behalf of a given person, health centre, or institution.

Advertising the need for an organ or the availability of an organ is not permitted. At present, this infraction has no legal

---

9. Article 6 of RD 1301/2006 ensures confidentiality of all data related to the donor's health, and the outcomes and traceability of his or her donations. It further states that personal data will be treated in a confidential manner and will only be available for the interested parties, and where necessary, for the legal authority to carry out commended functions. RD 1720/2007 of 21 December, developing the Organic Law 15/1999, defines in Article 5.1.g) "datos de carácter personal relacionados con la salud" (personal health-related data) as "las informaciones concernientes a la salud pasada, presente y futura, física o mental, de un individuo. En particular, se consideran datos relacionados con la salud de las personas los referidos a su porcentaje de discapacidad y a su información genética" (an individual's past, present and future, physical and mental health data, particularly, information concerning the extent of disability and genetic information).

When the criminal responsibility of a corporation falls within Article 31bis, temporary closure from 2 to 5 years of its establishments will be enforced, as well as confiscation of goods, products and benefits gained from the offence.

repercussions, however, the Criminal Code Reform Project, currently under parliamentary proceedings, categorises this type of behaviour<sup>10</sup> as a criminal offence when they are related to “illegal trafficking of human organs”. Advertising the availability of your own organs for donation is an infraction of the administrative transplantation regulation, but it does not imply criminal liability.

The donor’s family members will not be able to know the recipient’s identity and vice versa, meaning circulation of information which could be directly related to graft removal, transplantation or implantation should be avoided. Directly interested parties are naturally excluded from this restriction.

**Non-remunerated donations:** The donor must not receive any type of financial gain for the donation, nor may the recipient be requested money for a transplanted organ. However, the principle that the donation must never cause financial burden for the donor must be respected, as indicated in Law 30/79.

**Equity:** Choosing and gaining access for possible recipients must be performed equitably, ensuring equal opportunities to treatment. However, we have to take into account and consider that the main principle of organ transplantation is to improve the recipient’s health and quality of life.

**Minimising transmission of illnesses:** The necessary measures must be taken to reduce this effect.<sup>11</sup>

#### IV. Obtaining living-donor organs

Obtaining living-donor organs is regulated in the implementing regulation that supplements Law 30/79 and

extends on some of its conditions. The following is required by Royal Decree for living-organ donation:

1. The removal of the **organ or part of organ**<sup>12</sup> is **compatible with life** and the function of that organ can be adequately and safely compensated by the donor’s body.
2. Organs must not be removed from donors that have not reached legal age, even when parents or tutors have provided consent.
3. Living-donor organs must not be removed (or where applicable) used in cases where it could be suspected that consent has been given for financial gain or there is social or psychological coercion.<sup>13</sup>
4. The **healthcare centre’s Ethics Committee must issue a mandatory** (but not binding) **report** for every case.

The Royal Decree reiterates that a doctor not involved in organ removal must confirm that the donor is healthy and mentally competent, using the relevant information. Furthermore, it details the need to provide the donor with comprehensive information regarding the inherent risks associated with the intervention, foreseeable consequences to his or her physical and psychological health, possible repercussions on his or her personal, family and professional life and the benefits that the recipient is expected to gain.

The issues above will be accredited by a certified doctor that will make necessary reference to the health, information provided, and the response and motives freely expressed by the donor, and where necessary, to any sign of coercion. The certificate will include all the names of the other healthcare providers that may have been involved in the process with the certifying doctor. If the civil registry judge deems it

10. The Criminal Code Reform Project is actually in the process of adding article 156bis, with the following content: Those persons which promote, favour, provide or advertise the illegal procurement, traffic or transplantation of human organs from third parties will be punished with 6 to 12 years imprisonment for vital organs or 3 to 6 years for non-vital organs. If the organ recipient is aware that the transplantation was performed with an illegal organ, the recipient will be punished in the same manner as above. However, the penalties may be decreased by one or two levels, depending on the circumstances of the offence and the guilty party.

11. Article 2 of the RD 1301/06 of 11 November regulating activities associated with obtaining human cells and tissues for use in humans, includes the definitions “efecto adverso grave” (serious adverse effect) and “reacción adversa grave” (serious adverse reaction), among others, which considers the likelihood of an illness being transmitted to the recipient.

12. Definition of organ: any differentiable part of the human body that consists of different tissues which maintain their structure, vascularisation and ability to function physiologically in a relatively independent and sufficient manner (Article 3, RD 2070).

13. The Criminal Code Reform Project considers a new article, 156bis, which specifies that it is a criminal offence if the organ recipient is aware that the transplanted organ is of illegal origin. It does not seem that a recipient who accepts an organ from a donor who is motivated by any of the conditioning factors referred to in the Royal Decree is included in this offence. The offence specified in this provision always refers to “tráfico ilegal de órganos humanos ajenos” (illegal trafficking of human organs), not considering an organ donation as illegal trafficking when any of the conditioning factors mentioned exist (except for the financial gain).

necessary, the doctor may gather information directly from these colleagues.

**The donor must give his or her consent before the Judge responsible for the civil registry where the intervention<sup>14</sup> is to take place**, in the presence of:

- a) The doctor that certified the donor's health and circumstances (those healthcare providers that may have collaborated do not necessarily have to be present).
- b) The transplant doctor.
- c) The person who, according to the centre's authorisation document, should give his or her approval of the intervention.

The authorisation document will be signed by all parties present, which may oppose the donation if they were to doubt the donor's consent in any way.

With the purpose of verifying that the donor's consent is serious, well-reflected and supported, a minimum of 24 hours between authorisation and removal has been established by law. During this period the donor is able to withdraw consent. Naturally, the donor is equally able to withdraw up until the very last moment before the intervention.

The consent's validity is legally the most important aspect in living donation, as the removal of an organ from a healthy person could be considered a serious criminal offence, as indicated in Article 149 of the Criminal Code. Although it is clear that Article 156 of the Criminal Code absolves responsibility in these cases, it shall only occur when the donor has given free, valid, conscious and expressed consent. There is however one exception: when consent is corrupted or due to financial or material gain.

### **3. NEW CHALLENGES FOR LIVING KIDNEY DONATION: CROSSOVER DONATION. ALTRUISTIC DONATION: THE "GOOD SAMARITAN"**

#### **I. Crossover donation**

Living donation between unrelated or unemotionally related people poses the question whether this type of donation may be voluntary, altruist and non-remunerated.

Legislation among Ibero-American countries varies in this respect, and while Argentina or the Dominican Republic

require donors to be both genetically or emotionally related to the recipient, the only condition needed in Chile or Costa Rica is that the living donation is performed for a specific person. Some regulations can be placed in the middle, such as that of Venezuela, which regulates that the donor-recipient pair must be genetically related, although it is accepted that the public authorities may authorise donation between strangers.

As we have explained above, the Spanish regulation only requires the donation to be for a specific person, and does not have to be performed between two genetically or emotionally related individuals. We have also stated that this requirement must be interpreted as in the last point made by analysing the content of the Law 30/79.

Suspicion may arise from non-directed donation that the donor may have been remunerated or that the motives are not solely altruistic. We can define altruism as a disinterested concern for the well-being of others, meaning that this suspicion can be ruled out if the donor's motive is assessed and confirmed to be exclusively for the good of the recipient's health and quality of life. This may be achieved by drafting a psychosocial report on the donor which confirms his or her real motivation and provides information about his or her employment, financial and family situation.

In crossover donation, the donor's main interest is to benefit someone who he or she is related to in some way. That is why the donor decides to remain a donor, even if the recipient is unknown in the end. The donor knows that the other donor is donating to his or her relative, and that that donor, also a stranger to the former donor, is aware that by remaining willing to donate, the initial purpose will be achieved, i.e. that the person who he or she wanted to donate to, but was not compatible to, will receive a much-needed organ.

The donation is therefore not a conditioning factor (in that case, as we are aware, it could be withdrawn), but a legally valid condition that may be expressed in the following way: "I am donating because you are" (condition) and not "I am donating so that you do" (conditioning factor).

The objective which is hoped to be achieved from a health policy view is also covered by the Law, as it aims to overcome the current imbalance between the number of patients on the kidney transplant waiting list and number of donors. In recent years, deceased donations are being accepted from increasingly older people and/or those with associated illnesses, from deceased non-heart beating donors and, lastly, from non-related living donors, which fully

---

14. "Localidad de que se trate" (where the intervention is to take place) is developed in Article 9.4 of RD 2070/99.

comply with legislation on organ removal and transplantation.

In addition to the other living donor conditions (donor of legal age, competent, well-informed, etc.) this type of donation must comply with the following requirements to be legally valid: the unknown donor, willing to donate for his or her relative, is donating for the benefit of the first donor's relative, and that this first donor willing to donate for his or her relative is donating for the benefit of the unknown donor's relative.

Crossover kidney donation is therefore a simultaneous donation which develops from a previous will to donate, and is solely for the benefit of improving a specific recipient's health and quality of life. As such, and given that the related donor-recipient pair are incompatible, the donor remains willing to donate to a stranger because "someone else is to donate to my relative, who is the person that I want to help". This donation is therefore based on an exchange between the donors who were already willing to donate to their relatives but were unable to, allowing the recipients to receive an organ.

As we have stated, this donation method is completely legal within current Spanish legislation, even when transplantation is not hindered by incompatibility between an emotionally-related donor-recipient pair and it only entails a real benefit for crossover kidney transplantation (e.g. gain age). This type of donation would also comply with existing regulation, as the therapeutic objective and restrictions determined by recommended ethics of biomedical research and fundamental human rights are maintained (i.e. right to life and health).

## II. "Good Samaritan" donor

This donor is someone who donates to a complete stranger (whether identified or identifiable by means of a registration

number or waiting list) with the sole purpose of improving the recipient's health and quality of life. This donor complies even better than any other donor with the legal requirements that the donation is voluntary, altruistic and non-remunerated.

The problem that may arise with this type of donation is the same as that for crossover donation: finding out whether there is a hidden motive (mainly for financial gain) which prevents consent from being deemed valid. The new Article 156bis of the Criminal Code<sup>15</sup> does not specifically state that trading with your own organs is an offence (although the recipient could be an offender if he or she pays for it). However, it is clear that this type of donation could never be accepted.

There are many procedures that can ensure that the donor's motive is altruistic i.e. psychological assessments, reports from social workers, structured questionnaires, questioning the donor about their employment, financial, personal and family circumstances, etc. Furthermore, the donor must, of course, consent to all of these procedures, and the results must be presented before the civil registry judge, who will assess whether the donor's consent is conditioned by financial gain, social or psychological circumstances.

Legally allowing living donors donate to patients on the waiting list, considerably reduces (if not prevents) the risk of remuneration being hidden behind the will to donate. The recipient would therefore not know the donor and this would prevent any type of monetary transaction between them. The greatest problem would arise if, in order to obtain the most successful transplant, recipients were chosen with little attention being paid to whether the organ is distributed fairly. In these cases, it seems that there would be some sort of clue which indicates a possible recipient or reduced number of recipients from the beginning of the process, meaning that maximum efforts should be made to guarantee that the donation is altruistic and non-remunerated.

---

15. See footnote 10 (article 156bis of the Criminal Code Project).