



Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

**THE BIOETHICAL PROBLEM OF THE KINDEY TRANSPLANT
FROM A NON-BLOOD RELATED LIVING DONOR**

17th of October 1997

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INTRODUCTION

The National Bioethics Committee has always been very hesitant in taking position on bioethical issues and problems already regulated, at least in our country, by an appropriate law: both for a kind of dutiful respect towards legislators and their authority, as well as, especially, because our Committee (and more in general all National Committees) holds the strong conviction that its competence should involve only those bioethical issues that are explicitly “cutting-edge”, that pose really new dilemmas and about which public opinion still has no truly adequate judgement – even political.

The bioethical problem of the kidney transplant from a living donor, especially non-blood related, does not seem to be one presenting the characteristics abovementioned: in fact, for more than thirty years, there has been a specific law regarding this matter. When however the NBC received, on the 25th of January 1997, Prof. Girolamo Sirchia’s request of an opinion¹, it immediately saw an opportunity to make an exception to the norm it generally follows and to answer the request positively. The issue of the kidney transplant from a non-blood related living donor is gaining a factual relevance unimaginable until a few years ago, both for the tragic lack of organs, which makes the conditions of many patients for which a transplant seems the only plausible solution, objectively desperate (and not only from a physiological point of view, but also, and for some especially, from a psychological one), as well as for the new importance the problem has achieved not only in Europe, but I would say in the whole world. In its answer to Prof. Sirchia’s question, the Committee stressed its profound conviction, according to which organ donation – and in particular from a living donor – even if it can be qualified as a supererogatory act, cannot but have a very high ethical and bioethical appreciation – as well will realise those who will attentively read the following pages – of the objective dangers unavoidably linked to this practice and that, with the passing of the years, tend inevitably to increase, rather than diminish. From this, the NBC’s conclusive appeal to legislators and to the need for them to assume, or in any case to continue to assume, a rigorously prudent attitude in case they decided to eliminate or at least limit the exception (anticipated only in kidney transplants) to the general rule which prohibits organ donations between non-blood relatives.

To answer Prof. Girolamo Sirchia’s question, a “Working Group” was instituted consisting of Prof. Barni, Prof. Beniciolini, Prof. Bompiani, Prof. Cattorini, Prof. Manni, Prof. Zanella, who – taking advantage of Dr. Roberta Sala’s precious collaboration (who I here sincerely thank on behalf of the whole Committee) – elaborated the draft of an “opinion”. This draft was brought to the attention of all the Committee members and discussed in depth; finally, in the plenary meeting of the 17th of October 1997, the final text, printed here, was definitively unanimously approved.

17th October 1997

The President
Francesco D’Agostino

¹ Prof. Sirchia’s request is reported in this booklet’s appendix: the reader will, in this way, be better able to understand the “starting point” of the Committee’s work and especially the importance of the bioethical preoccupations which persuaded Prof. Sirchia to ask our opinion.

EXAMINATION OF THE REGULATIONS IN FORCE IN SOME EUROPEAN COUNTRIES

The National Bioethics Committee decided that the problem of the “transplant from a living donor” (that is, the removal of even numbered organs, like kidneys, but also in a more general sense, of parts of the liver, and/or of regenerative tissues) had to be considered for the developments that this practice has had in the last few years.

In formulating this reflection, it was considered appropriate to examine Italian laws first, then the ones in force in other European Countries and the European Union’s bills produced in the last few years by the Council of Europe, which found recent definition in the “Convention on Human Rights and Biomedicine” (approved on the 19th of November 1996 by the Committee of Ministers of the Council of Europe with the support – on the 4th of April 1997 – of Italy).

Without hoping to exhaust the topic, we will indicate the regulations in force with regards to the “removal from a living donor” in some European Countries.

1) Italy, Law of the 26th of June 1967, on kidney donation from a living donor

The law anticipates the possibility, although remote, to resort to the *transplant from a non-blood related living donor*, parent or not, only and exclusively in those cases in which the receiving candidate does not have any blood relations available or suitable for the transplant.

Therefore, the law stresses the exceptional character of such procedure, only applied to kidney donation.

According to article 1, the law allows this type of intervention as an “exception to the prohibition in article 5 of the civil code”.²

From the study of these two directives (art. 5 of the civil code and the law of the 26th of June 1967) we can deduce the following rules:

- 1) legitimacy of the removal of tissues;
- 2) absolute illegitimacy of the removal of odd numbered essential organs³;
- 3) general illegitimacy of the removal of even numbered organs, except kidneys.

Art. 2 of the Law 458/68 states that the donor must be:

- over 18,
- conscious and of sound mind,
- aware of the limitations of kidney transplant therapy,
- aware of the personal consequences and expressing explicit and informed consent.

² As known, art. 5 of the civil code forbids acts of disposition of the our own body, when they cause a permanent reduction of our physical integrity or when they are in any other way against the law, public order or morality.

³ The issue, today, is discussed in relation to the removal of “parts of organs”, more or less partially regenerative (see for example the epathic lobe), which could be part of the legitimacy of the removal of tissues.

The same Law 458 also states that the act of donation:

- is gratuitous,
- is completely free,
- can always be revoked,
- must not raise any rights to demand from the receiving patient.

The magistrate superintending the authorisations must be able to ascertain all these conditions and he is the one – from a legal point of view – supervising the verification of the entire procedure.

This, with regards to healthcare, must happen in specially authorised Centres and from particularly qualified health officials, who are themselves authorised. Therefore, health officials don't have the abovementioned duties, but must (art. 3) simply express "a technical judgement" to draw up in a specific report stating the donor's suitability and the existence of the clinical indication to the transplant into the patient.

From what summarised, it seems evident that the 1967 Italian law is particularly careful to satisfy some ethical conditions, especially for the donor's protection, whose – supererogatory – act must be absolutely protected. For this reason we stress the need for the donation from a living donor is free, spontaneous, altruistic and proportionate to the expected benefits (so that the organ donation from a living donor would be "extreme ratio"), as well as to the donor's quality of life, which can be reasonably expected after the donation.

Despite the fact that Italian legislation is in favour (but paying attention to the donor) of the donation from a living donor, and in art. 6 declares any kind of private agreement which involves a financial compensation for the donor in order to push him/her into the act of disposition, there are still today no rigorous pronouncements with regards of the sale of organs from a living donor.

In fact, Italian legislation simply states that any private agreement involving a financial or other compensation in favour of the donor, in order to persuade him/her to the act of disposition and destination, is null and void. Anyone who carries out a mediation in a kidney donation for financial gain is instead punishable by law.

2) Belgium, Law of the 13th of June 1986

It anticipate the donation from a living donor over 18.

The donation from a living donor, if it entails consequences for the donor, is allowed only if the life of the receiving patient is in danger (art. 6).

The donation from a living minor is possible if it does not involve serious consequences for the donor "if the removal of organs or tissues from a living person does not normally have serious consequences for the donor or if the organs or the tissues in question are regenerative and destined for transplant in a brother or sister, the removal can be carried out on a person who is not yet 18 years of age" (art. 7).

Belgian legislation does not seem to adequately protect the donor. Even in the case of eventual damage, the priority seems to be the receiving patient (even though, obviously, his/her life is in danger).

There is still some ambiguity in the dispositions of art. 7, in which it is not clear what donations are allowed to the donor who is a minor, if only that of regenerative tissue or even that of a regenerative organ (this is about, probably, the compensatory effect of the residual kidney through hypertrophy).

3) Denmark, Law number 402 of the 13th of June 1990

Danish law allows the removal from living donors of “tissues and other materials of biological origin” for the purpose of restoring or curing the health of another person who has given consent.

The law also anticipates that the donor can be a minor, but he/she must give his/her consent with the approval of his/her legal representative.

Danish legislation anticipates a monetary fine for anyone speculating on organ donation.

Danish law is not clear about the type of transplant, it does not clarify whether this regards regenerative organs or not, and it does not establish which organs can be taken from a minor.

It emphasises the request of consent from the minor donor, for who in addition does not have any particular protection, as everything is entrusted to the legal representative.

The monetary fine inflicted on who would eventually speculate on the transplant is not convincing, because it seems to introduce a quantitative assessment of the organ's value, which we instead want to avoid.

4) France, Law number 94-653 of the 29th of July 1994

Title II of the Law regards the “protection of the human body”. Many articles are dedicated to the fact that anybody who should have a financial gain from the removal of organs or tissue or other biological material can be punished, as well as anybody who should remove them without the donor's consent (articles 511-2/8).

With regards to the removal from a living donor, the law allows it:

- in the therapeutic interest of the recipient;
- on condition that the recipient is *blood related*;
- in case of need the donor can be the *husband or wife*.

French legislation is effectively similar to Italian legislation.

The removal from a minor is allowed only:

- for regenerative tissue,
- between brothers,
- with the consent of the parental authority,
- on condition that the minor does not object.

We must stress the importance recognised to a sort of consent from the minor which – although it does not exceed the responsibility and role of the parental authority – mediates an unshakable refusal.

5) Great Britain, Organ Transplant Law, 1989

English law *forbids (and punishes) commercial transactions* of organs destined for transplant and it restricts the transplant between non-blood related people.

English law discusses the commercialisation of organs at length, anticipating all the cases in which a crime can be committed.

It limits the transplant between living patients only between *genetically related* people.

The blood relation must be proved by undergoing procedures.

Exceptional cases of transplant between *non-blood related* living patients are allowed on condition that the absence of any kind of payment is ascertained.

6) Norway, Law number 6, of the 9th of February 1973

Norwegian law anticipates the removal, in the therapeutic interest of other people, of organs or biological material from living donors:

- who give their consent;
- whose life or health are not at risk.

Minors can be donors in exceptional cases and with their legal representative's consent.

It is interesting that the minor's consent is asked for, without however clarifying if all organs can be removed or only the regenerative ones. The donor's protection seems entrusted only to the respect of the will expressed by the legal representative.

7) Spain, Law number 30, 27th of October 1979

Spanish law emphasises the gratuitousness of the removal. No compensation is legitimate.

The living donor must be over 18 and legally capable.

The donor must give his/her written consent.

The removal from people unable to give a valid consent is forbidden.

The transplant must be carried out in the therapeutic interest of the recipient.

8) Crown's Decree, number 426 of the 22nd of February 1980

The following aspects are stressed:

- the donor must be above 18 and legally capable;
- the donor must be in a health condition that is compatible with the removal;
- the removal must not disproportionately compromise the donor's state of health;
- the removal must have a good *chance* of success for the recipient.

In addition, the donor must undergo a discussion with a different doctor from the one who will carry out the removal, so that the *real availability and spontaneity of the donation can be ascertained* (that is, the doctor must inform him/her of the physical and psychological consequences of the removal and make sure that the donor is truly free and not eventually psychologically forced to donate).

The donor can also withdraw his/her consent at any moment.

The Spanish decree seems to go in the direction of a (right) protection of the living donor, in order to accurately determine whether he/she has freely chosen to donate an organ.

Maybe an accurate analysis of the reasons for the donation and of the conditions of availability to the act of donation, could guarantee the legitimacy of the removal even between non-blood related patients (an analysis aimed at avoiding, as mentioned above, illegal practices like the sale of organs).

9) Sweden, Law on Transplants number 190 of the 15th of May 1975

Swedish law allows the removal of organs or biological material from a living donor:

- who is over 18, legally able and has given *written consent*;
- *who is a minor or incapable* if there are “the medical premises for the removal of biological material for transplantation”:
- with the legal representative’s consent,
- the health authority’s authorisation,
- in the absence of the donor’s eventual refusal.

Any removal that could harm the donor is therefore forbidden.

It is not clear whether, with regards to biological material, Swedish law is talking about regenerative tissue or even non-regenerative organs.

10) Sweden, Transplantation Act, 1st of July 1996

In 1996, Sweden reviewed his 1975 law on transplants.

A very interesting premise is that the “basic principle is that the use of organs from a living donor must be reduced to a minimum. The fundamental rule is that non-regenerative tissue and organs can be removed only from blood related or in any case close family donors”.

With regards to living donors, it is stated that:

- the donor must be informed of all the risks and consequences that could affect him/her;
- the donor must give a valid and informed consent;
- the transplant cannot be carried out if the risks for the donor are unacceptable.

In addition, the possibility of psychological pressures on the donors is also taken into consideration: unsure donors could decide to donate anyway because accepting it seems easier than knowing to frustrate their relative’s expectations.

The donor of *non-regenerative* organs should be a blood relative or at least a close family member (*the husband/wife or the live-in partner*).

This restriction to relatives is due to the necessity to limit the danger of commercialisation.

The incapable donor is legitimated only if it is a relative and if there is no other compatible donor available. Anyway, the authorisation of the *National Board of Health and Welfare* is needed.

In any case, the removal from an incapable donor cannot be carried out against his/her will.

A new development of the 1996 *Swedish Transplantation Act* is the acceptability of live-in partners, as well as family members, as donors, therefore without the need of the matrimonial link (maybe a few years old) between the donor and the recipient.

The attention to the possible risks of psychological pressure exercised on the donor is laudable, especially in the case (often overlooked) of brother donors, who are emotionally involved and psychologically easily influenced.

11) Switzerland, Medical and Ethical Guidelines for Organ Transplants, 8th of June 1995

With regards to the removal of organs from living donors, it is admissible that donor and recipient are *blood relatives* or have a *close emotional bond*.

Organ allocation must happen according to a principle of equity and justice.

The inclusion to the waiting list must be carried out on the basis of medical considerations and not material or social ones.

In the case of more than one potential recipient, the allocation of an available and compatible organ must happen according to the patient's place on the waiting list.

In case of shortage, the recipient must be a patient resident in Switzerland.

EUROPEAN COMMUNITY REGULATIONS

The European Community Bodies have taken an interest – at different times – in organ transplants from a variety of points of view, with the following documents:

- Resolution (78) 29, on the harmonisation of the laws regarding the removal, implantation and transplant of substances of human origin (European Community Council Committee – meeting of the 11th of May 1978).
- European Parliament Resolution on organ banks (Document 24 of the 27th of April 1979).
- European Parliament Resolution on organ transplants (Document 15 of April 1983, on the same topic).
- Resolution of the Health Ministers Council assembled in council on the 11th of November 1991, relative to the fundamental choices in the health policies sector (Paris 16-17th November 1987).
- European Parliament Resolution of the 14th of September 1993, regarding the trade of organs for transplants.
- “Convention for the protection of human rights and biomedicine” of the Council of Europe (1996), in articles 19 and 20, relative respectively to the donation from a living subjects able to consent (article 19) and in subjects unable to consent (article 20).

The European Parliament *Resolution* of the 14th of September 1993 has particular value in suggesting national disciplines aimed at forbidding the trade in organs and any abusive or criminal form of removing them.

With regards to the “donation from a living donor”, which particularly interests this document, it must be observed that article 6, letter d) literally invites to the “recourse as much as possible to living donors of the same family for kidney transplants”.

This “point of view” was, evidently, pushed forward by the lack of organs coming from cadavers, compared to the demand.

Articles 19-20 of the Council of Europe *Convention for the protection of human rights and biomedicine*, as approved by the Ministers Committee on the 19th of November 1996, have more substance.

The text follows:

Chapter VI

Organ and tissue removal from living donors for transplantation purposes

“Article 19 (General rule)

1. *Removal of organs or tissue for transplantation purposes can be carried out on a living donor solely for the therapeutic benefit of the*

2. *The necessary consent as provided for under article 5 must have been given expressly and specifically, both in writing and in front of an official body.*

Article 20 *(Protection of persons not able to consent to organ removal)*

1. *No organ or tissue removal may be carried out on a person who does not have the capacity to consent under article 5.*
2. *Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:*
 - i. *there is no compatible donor available who has the capacity to consent;*
 - ii. *the recipient is a brother or sister of the donor;*
 - iii. *the donation must have the potential to be life-saving for the recipient;*
 - iv. *the authorisation provided for under paragraphs 2 and 3 of article 6 has been given specifically and in writing, **in accordance with the law and with the approval of the competent body.**⁴*
 - v. *the potential donor concerned does not object”.*

The disposition is completed by Chapter VII, which reads:

Chapter VII

Prohibition of financial gain and disposal of a part of the human body

“Article 21 *(Prohibition of financial gain)*

The human body and its parts shall not, as such, give rise to financial gain.

Article 22 *(Disposal of a removed part of the human body)*

When in the course of an intervention any part of the human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures”.

A few details must be stressed:

⁴ The CDBI text only adds: “by law”. The Assembly introduced a more articulated text:… “in accordance with the legal authority entrusted with the protection of children”.

a) In the text of June 1996, we find the following statement (old article 18, subsection 1):

“1. According to this chapter, the expression “organ removal” extends to the removal of organs or tissue for transplantation or grafting purposes, excluding ovaries, testicles and reproductive cells. This does not apply to blood transfusions.”

It was deemed appropriate to eliminate this from the final text, which does not contain any express prohibition to the donation of genital glands anymore.

b) The *Rapport Explicatif* further clarifies that it is necessary:

- a specific consent from the donor, in writing or expressed in the presence of a public officer like, for example, a judge or a notary;
- a reasonable expectation of benefit for the recipient, whose need for a transplant is known before the removal;
- in addition, it clarifies that the dialysis treatment must not be considered sufficient to produce, in terms of quality of life, a result comparable to that obtained with a kidney transplant.

With regards to the authorisation for the removal of tissue from incapable donors (in practice today this refers to bone marrow, but it does not exclude other tissue in view of the progress of medicine), the justification of the act is the following:

- the removed tissue regenerates and the bone marrow can be transplanted only between genetically compatible persons, often brother and sister;
- the tissue exchange between brothers can be justified, where necessary, by the principle of mutual help between close relatives;
- the removal is allowed only when the recipient’s life is in danger.

In any case, the *Rapport Explicatif* stresses the prohibition of removal where there is a resolute and unshakeable objection on the donor’s part.

- c) The condemnation of any form of commercialisation stands, both in the *Convention* and the *Rapport Explicatif* texts.
- d) An additional “protocol” is required to further clarify the issues relative to the removal of organs and tissue from living donors for transplantation purposes (during the writing of this document up to now).

BIOETHICAL EVALUATIONS

1) Kidney transplant for a non-blood related living donor: instructions and outcomes.

We need to start from the consideration that medical international literature highlights, if the technical-surgical conditions and, obviously, the condition of the organ to transplant are equal, a superimposition of the curves of survival of kidneys removed from cadavers and kidneys removed from non-blood related living donors. This outcome, documented in many publications, is perfectly in line with our immunological knowledge, as the biological histocompatibility between recipient and donor, regulated by the genetic system HLA, generally should not distinguish the cases of a living donor and a deceased donor. Nevertheless, the probability of surviving a kidney transplant is higher if the couple donor-recipient is histocompatible and this is usually more probable (but not certain) when the couple is genetically related (spouses are relatives but strangers from a genetic point of view).

As there is an equal chance of survival from kidneys removed from cadavers and from blood related living donors, it is necessary that in assessing the usefulness or benefit for the recipient the ethical evaluation focuses on other aspects. For example, taking into account that the possibility of receiving a kidney transplant from a cadaver is low (in Italy around 10 transplants per million inhabitants are carried out, whilst the demand is estimated at 40 transplants per million inhabitants) and that normally the patients wait about 4 years to receive a transplant, whilst the donation from a living donor allows a quicker access to the transplant, we believe that we have to take into consideration also the following factors:

- a) the biological-clinical wear of the patients due to the time spent under dialysis;
- b) the psychological wear of the patients due to the time spent under dialysis;
- c) the economical-social impact of dialysis treatment in comparison to the transplant therapy.

Although literature does not show us any outcomes with regards to patients receiving a transplant exclusively from non-blood related living donors, we have not found significant differences in relation to the psychological state, the quality of life, the long term psychological adjustment, in patients being transplanted with a kidney from a cadaver and from a living donor (L. Schlebush *et al.*, 1989; B. J. Pillay, 1992).

2) Ethical-deontological problems

Although the choice of a kidney transplant from a cadaver in contrast to that from a living donor is absolutely believed to be a priority, also for obvious ethical-deontological reasons, it is important to highlight that international literature does not seem to stress the existence of particularly serious risk factors for the physical health of the kidney donor. Naturally, the outcomes need a rigorous preliminary definition and pursuing: a) of biological standards of physical suitability to donation; b) of the

levels of technical-professional competence of the centres authorised to transplant operations; *c*) of the medical-welfare standards for the donors.

With these premises, many studies documented that mono-nephrectomy does not represent a long term risk factor for the donor's physical health (D. A. Odgen, 1983, D. Weiland *et al.*, 1984, S. L. Williams *et al.*, 1986, W. Bay *et al.*, 1987, J. Blohme, 1992). Bay and Hebert (1987) assessed a short term risk of death for 1,600 donors, about 0.06%. Bonomini (1991) confirms a very low incidence of short and long term negative effects.

In Norway, in which the quota of transplants from living donors reached the 40-50% of the total amount of transplants in the years 1989-1990, Talseth *et al.* (1986) re-examined 92% of all Norwegian kidney donors after 9-15 years since the nephrectomy, with particular focus on hypertension and renal functions, not finding any pathological effects different from those affecting the rest of the population. On the other hand, a 1993 Norwegian research (L. Westlie *et al.*, 1993) conducted on the "quality of life" (defined in terms of psychological state, social relations, somatic discomfort, physical and occupational functions) of 494 donors (primarily blood related) evaluated between 1 and 19 years after the kidney transplant, found values equal to those of a normal population of comparison, and better in the psychological aspects.

Even the research carried out by Gouge *et al.* (F. Gouge *et al.*, 1990) in 1990 in the U.S.A. found normal levels of subjective evaluation of quality of life in the donors in comparison to the normal population. Bonomini (1991) confirms a minimal incidence of negative psychological effects in the donors even in the long term and a continuation of 100% efficiency at work. Simmons (1983) followed, up to 5 to 9 years since the donation, a group of 230 blood related donors, finding that in 95% of cases they had a psychological benefit in terms of self-esteem and kept a positive attitude towards the donation.

In a study carried out in the USA, on 536 blood related donors (1986), whose nephrectomy happened in the previous 12 years, it seemed that no donors had psychological problems, due to the nephrectomy, such that they required the intervention of a specialist. Giving an overall evaluation of the effects of the donation, 92.4% felt that the nephrectomy had not been harmful to their health. The 96.8% stressed the positive attitude towards the donation.

Even the authoritative opinion of Aaron Spital (1988, 1989 and 1992) confirms the low incidence of negative effects, both clinical and psychological, to the point of hoping that the donation of a kidney from a living donor could be extended to include "willing, conscious, unrelated donors" (1988).

With regards to the fear/suspicion that the motivation to donate a kidney could be altered or invalidated by psycho-pathological disorder or by pressure/coercions external to the donor's free will, this risk does not seem confirmed in literature, even though it is not easy to identify it quantitatively. Already in Sadler's 1971 study and in the following one (1983) by Simmons, as in other works (C. H. Fellner *et al.*, 1971, R. L. Lawton, 1978), there is no evidence of psycho-pathological causes or coercive interventions to donate. In the study carried out in the USA study, on 536 blood related donors (M. D. Smith *et al.*, 1986) more than the 84% of the donors declared that they had received sufficient information about the donation. In substantial majority they indicated that not the relatives (85.8%), nor the friends (86.2%), or the health workers (93.7%) had tried to influence their decision. Around 14% stated to have received some pressure, especially not to donate, from relatives and friends.

From a more specifically ethical point of view, even if Fellner in 1971 defined the refusal to donate from non-blood related donors as “non-scientific, emotive and based on prejudice”, the answers to the 1971 Sadler’s investigation (H. H. Sadler, 1971), carried out in 54 transplant centres in the world, indicated a high level of diffidence for the human motivation to donate and a repugnance to use non-blood related living donors. Following reflections by many authors, as well as Fellner and Sadler, like Lawton (1978), Burley and Stiller (1985) and Spital (1987), however felt that this prejudice is unfounded and that the use of voluntary donors, even non-blood related, altruistic, over 18 and conscious, should be reconsidered, because of the limited availability of organs, of the increase of patients waiting, of the improved ability to select according to immunitary compatibility. In addition is more likely that a non-blood related but “*emotionally related*” donor is a true voluntary. We believe in any case that it is indispensable to carry out a psychological and social “screening” of the person and the context, with a professional psychological evaluation when necessary.

When the clinical and psychological requirements, as well as those of consent, are met, refusing a donor who is emotionally “related” or otherwise motivated to donate does not seem justified. In other words, it appears that the moral values of the free donation of a kidney cannot be a choice of transplant Centres but must be left to the free and conscious will of the individual. With regards to this, Spital in 1988 published the outcomes of an investigation carried out on the opinion of transplant Centres and the general population in the USA. Whilst 86% of transplant Centres was prepared to use blood related donors, the great majority was against the use of non-blood related donors. From the answers of 360 doctors (not transplant surgeons) and of 264 non-doctors, more than 90% would donate to a spouse, about 60% to close friends, more than 90% believed that those wanting to donate to a friend should be allowed to do it, and 70% agreed that the donation to strangers without compensation should be allowed. The same author (A. Spial, 1989, 1992) in a following inquest however observed that the opinions of the same Centres were beginning to change: of 100 Centres that had previously answered, 76% declared that they were prepared to accept donations from spouses, 48% from adult friends; but only 8% stated that they would accept the gratuitous donation from altruistic and conscious unknown adults. The author concludes that the use of voluntary and informed non-blood related living donors can be considered ethically acceptable and that the scarcity of organs does not allow us to refuse the donation from living donors if it satisfies the medical and ethical standards previously defined as satisfactory. Once these standards have been ascertained, and with the guarantee of proven professionalism of the transplant Centre, Bonomini (1991) expressed the conviction that “the dignity of the donor’s spontaneous choice to donate should be fully respected”.

A problem of a different nature, but one that deserves very careful consideration, is that often at the basis of a kidney donation from a person who is a stranger to the receiver, there could be an economic incentive. The T.F.O.T. states that the “sale of organs is immoral as it excludes the poor, mortifies the donor’s dignity, violates the principle of the ability to access services”; and it is therefore illegal in the USA⁵.

For all these reasons Singer – for example – suggests *extreme caution in accepting donations from living unrelated donors*.

⁵ T.E.O.T. Recommendations: U.S. Department of Health and Human Services, April 1986, page 36.

If, therefore, on the one hand there is a real risk that the donation is a masked form of sale, passed as a highly altruistic act, an expression of great solidarity, it must also be said that every argument called to limit, if not exclude, the donation of organs from a living donor is an argument based on prudence, as the donation itself is an act not only morally licit but in fact highly laudable. We observe that *“The risk linked to the transformation of the donation into a sale is not, evidently, intrinsic to donations, but is connected to human transactions, and also to those that should be based on the highest altruism”*.

CONCLUSIONS AND PROPOSALS

As it has already been documented previously, it appears evident that many of the laws in force are largely inspired to prudence in regulating transplants from living donors. In this way the T.F.O.T. (USA), although it does not exclude the LURDT (Living Unrelated Donors Transplant – transplants between spouses, friends), imposes an operative caution so that the donation is consciously offered merely for altruistic reasons; the *British Transplantation Society* admits the LURDT only for humanitarian motives; in France the transplant from a living donor is justified only if donor and recipient are blood-related and the spouse can also be considered a donor only in urgent transplant cases. Some transplant Centres in Germany (Monaco and Hannover) in the last few years have not carried out any transplants from living donors unless they had a data of HLA compatibility documenting the genetic identity between donor and recipient.

In 1987, the Council of Europe Health Ministers Committee approved a directive that advises against transplants from living donors in all cases, with the only exception being the transplant between HLA identical brothers. The considerations that determined the committee's position are the following:

- transplants between genetically identical subjects guarantees the best results in the long term, whilst the outcomes of the transplants from a living donor who is genetically non-identical or different are not substantially different from those achieved with organs from deceased donors;
- the shortage of organs from deceased donors penalises not only nephropathic patients waiting for a kidney transplant but many other patients who need a heart or liver or lung or tissue (obtainable from cadavers) transplant; transplants from living donors can “take away the responsibility” of the doctors and the personnel involved in finding organs, which would become a problem of the family.

However, faced with the evident shortage in organs from deceased donors, the European Parliament, in the Resolution of the 14th of September 1993, “invites” to the recourse, whenever possible, to living donors of the same family for kidney transplants.

As already seen, the “Convention for the protection of human rights and human dignity with regards to applications of biology and medicine” in chapter VI (*Removal of organs and tissue from living donors for transplant purposes*) article 19 (*General Rule*), subsection 1, reads: “Removal of organs or tissue for transplantation purposes can be carried out on a living donor solely for the therapeutic benefit of the recipient and where there are no suitable organs or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness”, without any reference to being blood relation.

From all these elements, it seems evident that removals from living donors still constitute a very limited hypothesis – which should not mean that every “offer” of availability is granted – but that there is a tendency, in any case, to consider it an evolution from the past.

With regards to *Italy*, the law of the 26th of June 1967, number 458, is still in force. It anticipates the LURDT as well, *but only in those cases in which there is a lack of possible blood related donors or when not one of them is suitable or available* (article 1, subsection 3): that is, the *residual hypothesis* is in force, which however - in the normal procedure – risks, according to some, to become something more widely practised.

It must be observed, in addition, that this is legally accepted situation, which has already been in place in some European Countries for some time, as we have documented.

It must be stressed, finally, that the topic for our country too, will have to be referred to the laws which will be enforced by the Council of Europe⁶.

Although current Italian law appears to be more protective of civil liberties than the Council of Europe Convention with regards to the living donor's life and health, as well as more careful in highlighting the need to gain a consent to the donation (a consent in which altruistic reasons for the donation are as much as possible demonstrated, so that it can be said to be a truly free consent and not extorted in some way), should we want to proceed *to the acceptance of the European Community law*, we should conclude that *the condition that there is a blood relation between conscious donor and recipient* (except in extraordinary cases) could be reformulated, taking into account the following observations:

- being blood related can in some ways be substituted by being related: even spouses could be considered living donors and not only, as expressed by law, in the absence of blood related donors (with the exception, naturally, of histocompatibility);
- the conjugal relationship should be reviewed in light of the fact that today a couple's stable relationship between people not legally married is "normal" (in his report, found in the appendix, Prof. Sirchia refers to couples who have been legally married for at least three years);
- in Italy, being blood related cannot be a guarantee of a spontaneous and gratuitous donation.

If we accept this hypothesis, we also recognise the reasons that prevailed in the European Council, leading, in the case of a "*conscious donor*", to favour the subject's "*principle of autonomy*" beyond any other constraint.

The "*principle of autonomy*" – evidently – cannot be recalled in the case of an "*unconscious donor*", who needs particular attention. If in this case we can invoke the principle of solidarity or altruistic love between family members, it must be however mentioned that organ donation is not a duty, not even between brothers, just as no-one can have a right to the organ "donated" by a brother. Between brothers there can be a psychological coercion to donate, that is, – as mentioned – unconscious and subtle psychological pressure can be exercised in favour of the donation.

If Italy felt the need to keep in force, without any changes, law 458/1967, it could put a "reserve" on articles 19-20 of the *Convention for the protection of human rights and biomedicine*, according to article 36, subsection 1, which reads: "*Every State and the European Community can, at the moment of signing the current Convention or at the moment of ratifying it, formulate reservations with regards to a particular directive of the Convention, as much as the law in force at that time in its territory*

⁶ As already observed, we are waiting for the passing of applicative "protocols" of articles 19, 20, 21 of the "Convention for the protection of human rights and biomedicine", which will better clarify any operative aspect of the cited law.

does not conform to such a directive. General reservations are not authorised in the present article”.

Other considerations must also be put forward regarding current Italian law.

The *medical-legal* moment that makes it possible, after the magistrate's decree of authorisation, to gratuitously remove a kidney from a living person even if not blood related, has been built on an explicit dispensation of the prohibition in article 5 of the Civil Code in force, which forbids any act disposing of our own body when it can lead to permanent biological damage. Legal and medical-legal doctrine has generally criticised the legislative set-up that transfers to the penal sphere a situation that is merely civil and contractual, extending in this way a possibility that would have been legitimised in any case, even in exceptional circumstances, when the danger for a subject's life cannot be easily overcome in any other way (article 54 penal code) and within a consensual agreement, inspired to very elevated reasons of solidarity, as it can happen in a very close blood and/or love relationship.

The recent extensive interpretation of article 32 of the Constitution, which stresses the protection of health, also subordinating it to the subject's will, highlights how every dispensation (always assisted by a specific law) can refer only to the interested subject and not others, putting into doubt, in some ways, the constitutionality itself of the law 458/1967.

In the end, the medical-legal evaluation of the abovementioned law, can currently only be inspired to maximum caution, *whilst we need to make every effort to avoid the commercialisation of organs.*

It could be considered desirable - in order to avoid the growing increase in the commercialisation of organs - a greater legislative rigour in punishing all the subjects eventually implicated in this practice: (the organ seller, the organ buyer, the mediator, the doctor who carries out the transplant), although we must conclude that an embitterment of the sentences for the crime selling and buying organs it's not a completely satisfactory solution if we care about the health of the potential seller and of the potential buyer, especially when considering the condition of pitiful need which they both must be experiencing.

It is important – however – to highlight that the request to introduce penal laws for organ traffickers and dealers (and not only fines), is presented to the various European States by point 10 of Resolution A 3-0074/1993 of the 14th of September 1993 on “Organs trade and transplants” approved by the European Parliament, and it was introduced in the recent French law on the protection of the human body (up to 7 years imprisonment and a 700.000 francs fine), and this position seems acceptable even in the hypothesis of a revision of the Italian law.

SYNTHESIS AND RECOMMENDATIONS

The NBC believes justified the preoccupations and the initiatives undertaken by the *North Italy Transplant* (NITp), which in the meeting of the 12th of September 1987, stressed how donations from non-blood related living donors must be limited to exceptional cases and after having ascertained the motives for the donation.

The NBC in fact shares the concern that the risk of a commercialisation of the organs comes from high demand and low offer: and it believes that the priority must be to put into practice all the measures capable of leading to an increase in the donation from cadavers, measures mostly of an informative and organisational nature, which are well known and of proven efficacy.

Also, we should not overlook the opportunity for a possible, soon-to-happen legislative revision of the Italian directive with regards to organs and tissue donation – offered by the abovementioned “*Convention*” of the Council of Europe – which would also reconsider donations from living donors and would make some high meaning and minimal risk procedures possible – or easier.

In light of the previous discussion, the NBC believes that, should there be a revision of the current laws, the following points should be stressed:

- there should not be a repeal of the principle of the serious assessment of immunological compatibility, for the recipient’s adequate protection;
- the removal from living donors should not take place in case of excessive risks for the donor;
- all eventual consequences for the donor’s health must be precisely communicated and clarified;
- donors must give a valid, free and informed consent;
- donors must be blood related or emotionally related to the recipient: close, non-blood related donors can be the spouse, the stable live-in partner or a friend, whose emotional bond, such to justify an altruistic act like the donation of an organ, can be effectively proven, but this should be limited to particular cases;
- the documentation relative to this emotional bond must be collected and made available for any eventual needs following a psychological/psychiatric conversation aimed at proving the true spontaneity of the donation;
- the donation must happen in the presence of and under the magistrate’s aegis, keeping in force the scrupulous assessment of all of the case’s elements, with the prospect that the magistrate might declare his/her refusal to the removal as well as the transplant. In this case we must add the possibility of a further pronouncement by the Tribunal, in the Council’s Chamber.

Within the frame of a growing ethical/deontological responsabilisation, in any case the matter relative to the donation-allocation of kidneys that have already been removed or have still to be removed, could be usefully given to the non-binding opinion of the Ethics Committee, with the understanding that the magistrate’s final judgement is compulsory in the case of removals from living donors.

In conclusion, we stress the NBC’s opinion in favour of an extension – although very controlled – of the removal from living donors, even those who are non-blood

related but only *emotionally related*, an extension that can be ethically shared, in principle and in itself.

However, given the real danger that acts apparently dictated by altruism or great solidarity are in reality either interested acts (where the prevailing interest is economic), or acts – even if not completely consciously – that have forced on people (talking about the not rare possibility of psychological pressure exercised on the donor), the NBC believes that the evaluation in “not simple” cases of organ removal needs a twofold reflection:

- purely on a moral level: for which we stress the legitimacy of the donation also between non-blood related patients, maintaining the condition of freedom, valid and informed consent, not excessive danger for the donor, which the current law already anticipates – from a moral point of view any act of real donation, even if it can be qualified as supererogatory, cannot but have a high level of appreciation;
- on a legislative level: for which, given the abovementioned real dangers, we believe that we need to entrust to the prudent attitude of the legislator the possibility of limiting or eliminating the already anticipated exception to the rule (the general rule that forbids organ donation from non-blood related donors) should we feel that such an exception could encourage a degeneration of the correct transplant procedure, especially in the direction of a trade in organs. The decision the legislator should make, should take into account these prudential considerations, in order to avoid – once a law has been ratified – paying a high price in terms of foreseeable negative consequences.

TABLES

ITALY – Annual evolution of kidneys “transplant movement” (*)

YEAR	1993	1994	1995	1996
Population (10⁶)	56.3	56.0	56.7	57.2
Kidney transplant from cadavers	661	830	1,094	1,121
PMI	11.7	14.8	17.9	19.6
Kidney transplants from living donors	132	119	107	118
PMI	2.3	2.1	1.9	2.0

(*) Data reported by “Newsletter transplant”, International figures on organ donation and transplantation – 1996 – Council of Europe, Vol 2/1.

PMI = prevalence for million inhabitants.

1996 situation of the activities of transplantation and donation from living donors in different European countries (*)

COUNTRY	Population (10 ⁶)	Kidney transplants from cadavers		Kidney transplants from living donors	
		Number	per million inhabitants	Number	per million inhabitants
Austria	7.8	347	44.5	18	2.1
Belgium	10.1	424	41.8	18	1.7
Czech Republic	10.5	389	37.2	5	0.5
Croatia	4.7	23	4.9	13	2.8
Denmark	5.2	136	26.1	42	8.0
Finland	5.0	175	34.4	3	0.6
France	58.8	1,581	26.9	57	1.0
Germany	82.0	1,887	23.0	129	1.6
Great Brit. + Ireland	61.9	1,624	26.2	180	2.9
Greece	10.0	46	4.6	60	6.0
Italy	57.2	1,121	19.6	118	2.0
Luxemburg	0.4	14	35	-	-
Norway	1.3	117	27.2	69	16.0
Holland	15.0	425	28.3	80	5.3
Poland	38.5	347	9.0	12	0.3
Portugal	10.0	400	40.0	3	0.3
Spain	38.4	1,685	43.8	22	0.6
Sweden	8.7	209	23.9	99	11.3
Switzerland	7.0	166	23.6	43	6.1
Hungary	10.3	260	25.2	-	-

(*) Data reported by “Newsletter transplant”, International figures on organ donation and transplantation – 1996 – Council of Europe, Vol 2/1.

PMI = prevalence for million inhabitants.

Kidney transplants from living donors. Donor’s safety

Study’s Nationality	Authors	Year	Number of cases	Medium-term follow-up	% morbidity	%mortality
USA	Bia M.J. et al.	1995	9,692	5	0.23*	0.03
France	Barrou B. et al.	1996	63	10	4.8**	0
Austria	Borchhardt K.A. et al.	1996	22	1	22.7***	0
Switzerland	Zurcher R.M. et al.	1996	28	1	30+	0
Holland	Beekman G.M. et al.	1994	47	7	23++	0
USA	Najarian J.S. et al.	1992	57	20	31o 23***	0
Sweden	Karlberg H.I. et al.	1991	490	10	1.5* 14++	0
Greece	Alexopoulos E. et al.	1991	86	5	13.9***	32.5o 0
Italy	Bonomini V.	1991	131	1	0.5* 11.8++	0

(1) case report of chronic kidney failure (Said R., 1996)

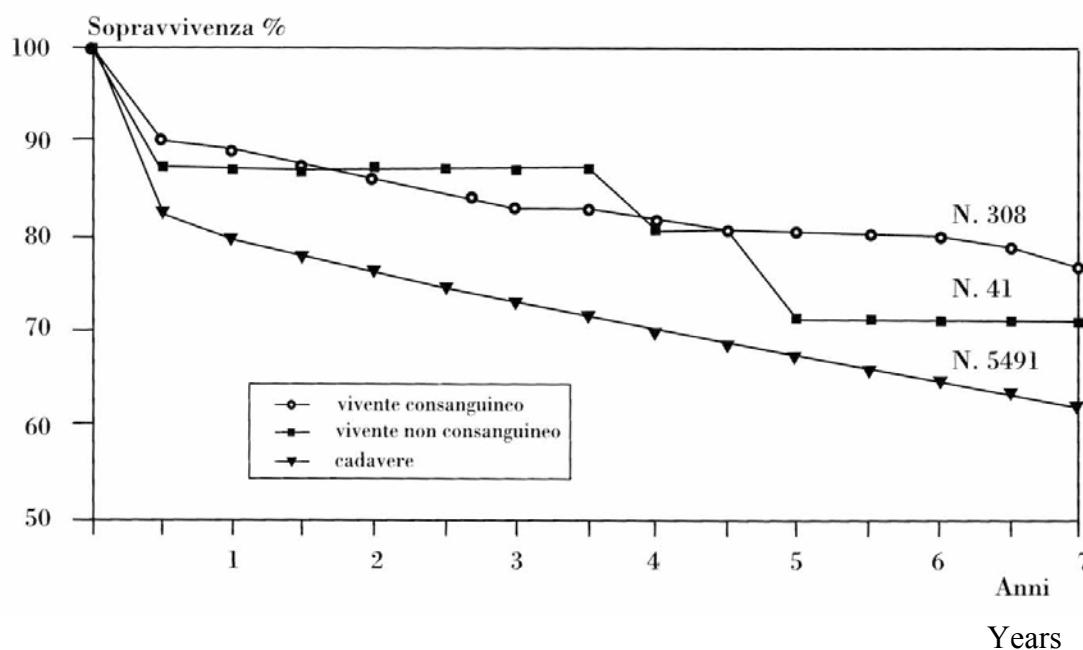
(*) serious or disabling complications; ** wound suppuration, pulmonary atelectasy; *** microalbuminuria. + hyperuricemia; ++ minor complications; or hypertension.

NITp – Kidney transplant

Long term survival of the kidney in relation to the type of donor

(1st of January 1983 – 30th June 1997)

Survival %

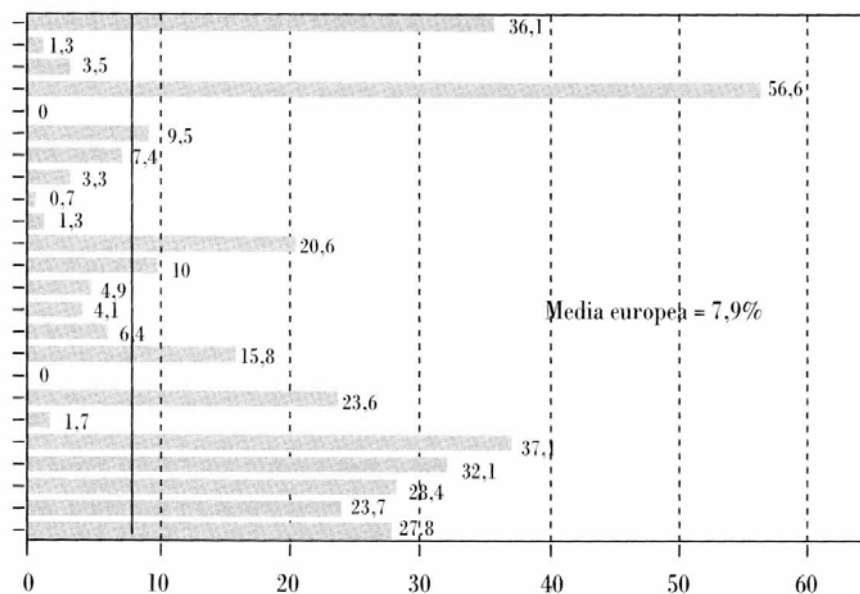


- Blood related living donor
- Non-blood related living donor
- ▶-Cadaver

Kidney transplants from living donors

Percentage report of the number of transplant from living donors carried out in comparison to the total of transplants in the world in 1996

Croatia
Czech Republic
France
Greece
Hungary



Italy
NITp
Poland
Portugal
Spain
Switzerland
United Kingdom
Austria
Belgium
Germany
Holland
Luxemburg
Danmark
Finland
Norway
Sweden
USA
Australia
Canada

Living/total transplants (%)

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