

Italian Legislation on Transplantation

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1. Introduction

Transplant ethics is at the centre of a range of anthropological, ethical and legal, medical and political issues. The transplant reflects the idea of person, the respect due to the deceased, the responsibilities of families, the voluntary donation and consent to it, the definition of death, the development of surgical techniques, the role of the state in regulating the public sphere of health promotion and those relating to citizens' choices¹. The purpose of this research is to document the Italian Legislation on Transplantation.

2. Acts of disposition on one's own body

The article 5 of the Italian Civil Code affirms that are prohibited any actions on one's own body when causing a permanent damage to physical integrity or when violating Law, public order or decency. This norm introduces a right

¹ AIDO, 2010

relating to personality, which is guaranteed also by the Italian Constitution at the article 32, that recognized the Right to healthcare as a right of the individual and a social right.

According to the disposition of the article 5 of the Civil Code, the right to physical integrity is the right to the enjoyment of one's own body in its wholeness and natural health. It is absolute right, indispensable and unavailable. Is generally prohibited except in cases of provision permitted by the same article and the consent for a rightful act of disposition can be revoked in any time. The limit places the irreversible damage as a discrimen between what is permissible (e.g. blood donation, expressly permitted and regulated by L. 592/1967) and what is prohibited (e.g. corneal transplantation as a living person, which would irretrievably impair the function of sight).

The reason of the norm, obtainable from the redaction made by the guard seals of the 1942 Code, concerned the principle according to which any subjective right can be recognized if not within the limits of the social utility. So, prohibiting any acts of disposition that can produce a permanent physical damage, the Legislator fulfilled the purpose to protect the physical integrity, recognized as an essential condition so that the individual can comply his duties towards the society and the family.

Then, the social utility and the quantitative and functional character of the physical decrease were the parameters through which the acts of disposition can be permissible or not.

However, in the majority of the cases, these parameters are unable to consent the realization of other values of the individual, regarding to which the physical integrity is just the mean and not the scope².

For that reason, the norm results inadequate, because it considers the permanent physical decrease only by a material point of view, without

² Rapisarda, 2016

considering the finality for which the act in question is provided. The lack of functionality is also evident from the numerous exceptions provided by ordinary legislation.

3. The evolution of the Informed Consent in Transplantation

A central point in the legislation on transplantations is the consent of the donor, with respect to which it has passed from an express consent to a presumed consent to the tacit-consent.

The presumed consent was introduced with the Law 644/1975, which stated at the article 6 that the removal from dead body not subjected to diagnostic or autopsy ordered by the judicial authority, is prohibited when in life the subject has explicitly denied his consent. Furthermore, article 7 introduced the possibility of written opposition by relatives (not legally separated spouse or, in the absence, children aged 18 or, in the absence, parents), with the exception of persons subject to diagnostic tests or to autopsy operations ordered by the judicial authority.

Then, the Law 91/1999 established another type of consent; In fact, the Law provides that Local Health Unities notify citizens of the request to declare their free will with regard to organ and tissue donation after deceased. After receiving such a request, citizens shall declare their free will with regard to the donation of organs and tissues of their bodies after death, and are informed that missing to declare their will is considered as consent to the donation.

4. Italian Legislation on Transplantation of organs by a living donor

The donation in life is strictly regulated in Italy by laws and protocols that define, among other things, operational procedures, any clinical contraindications for the donor and how to join.

The first type of donation in life regulated in Italy was about the donation of kidney on the 26th of June 1967, by the Law n. 458. The article 1 of the same law establish the first exception to article 5 of the Civil Code, affirming that it is allowed to have free of charge the kidney for transplantation between living persons. This derogation is consented for the parents of the recipient or relatives (children, siblings or non-parents of the patient who are of legal age). The elements that characterise the kidney donation in the law are:

- Free of charge
- Voluntary
- Conscious and of sound mind

These elements are strictly connected with the favour that the Italian legislator had regarding the health and protection of the donor. In fact, the art. 6 of the same law declares that any kind of private agreement which involves a payment or other compensation for the donor in order to convince 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.

The 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.

For this fact, is provided a careful assessment of the suitability of the donor, aimed at ensuring optimal physical and psychological health. An assessment that verifies the reasons for the donation, the knowledge of potential factors of risk and the real chances of transplantation in terms of organ survival and patient, the existence of an affectionate relationship with the patient (in absentia legal link) and the real availability of free and informed consent. In particular, adequate information related to the possible alternative treatments for the recipient must be provided to the donor, and the evaluation about the acceptability must be carried out by an independent team both from the patient and the professionals which perform the transplantation. Furthermore, the donor has the right to revoke the consent in any moment before the surgery. If the citizen does not express his/her will, the family (spouse, cohabitant more uxorio, adult sons and daughter, parents) has the right to go against the donation. Citizens can modify their declaration at any moment, and in this case, only the last declaration can be considered to be valid.

A problem arises in the case the donor is not a blood-related. As confirmed by the Italian National Bioethics Committee, 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. The reason lies in the extreme caution to make every effort to avoid the commercialisation of organs. However, the National Bioethics Committee stated in a report of the 1994 that the condition that there is a blood relation between conscious donor and recipient could be reformulated, favouring the so-called *principle of autonomy*.

The specificity of the problem is in the fact that in this case donor and recipient do not have any family or emotional bond, they do not know each

other and the gratuitous organ donation is carried out, as by law, through Organ Transplant Centres, University Institutes, Hospitals believed to be suitable also for scientific research. The National Bioethics Committee answered in the opinion requested by the Council of Ministers in 2010, affirming that Samaritan donation is legitimate and ethically significant for the solidarity motivation but, because this is a supererogatory act, it cannot be demanded morally, and even less legally.

To increase the possibility of Living Unrelated Donors in kidney transplantation between blood group incompatible pairs, it was proposed in 1986 a national network to exchange kidneys harvested from living donors with a blood group not compatible with their emotionally related recipients. This suggestion was proposed again in 1997 by Ross as a local program and by Park et al.⁸ This so-called crossover procedure allows living kidney transplantation also in cases of couples with direct positive cross-matches.³

The Italian National Transplant Centre has produced a document entitled "Protocol to perform kidney transplant from a living person in cross-mode". The document is the result of the work of an ad hoc Commission which began in 2005 and was discussed in a "Consensus Conference" convened in Rome, at the Istituto Superiore di Sanità, the 20 September 2006. Crossover kidney transplantation from living donor is allowed when donor and recipient are not compatible for the presence of antibodies against HLA or against ABO or for other reasons of incompatibility and the standard living donor transplant procedure is precluded. Donors and recipients who choose to opt for living donation in cross-over mode are registered in a single national register edited by the National Transplant Center that contains all the clinical and immunological information to identify the best match between donor and recipient and the evaluation of the outcomes of such transplants, as well as the follow-up of donors. The feasibility assessment cross-transplantation concerns

³ Bruzzone, Venettoni, 2008

not only clinical and immunological aspects but also ethical, social aspects, psychological. For this reason, a third-party commission is responsible for assessing both donors and recipient. The third-party commission has exclusively the task of verifying the free donation from part of the donor and the awareness of the risk to which it is exposed. This commission is independent from the donor, the recipient and the respective surgical teams. The first evaluation is carried out by a Part Three first at the regional level and or at the reference hospital, and then at the level of national (central) by a commission identified by the National Transplantation Centre. The commission national is composed of several specialists assessing the documentation submitted by the third party regional or corporate. The National Transplant Center is guarantor that kidney transplantation from living donor cross-checks are carried out in compliance with the rules in force and in monitoring the expected results⁴.

It's also recommended that this form of donation must be exercised respecting the mutual anonymity of the donor and the recipient and that the information given to the donor by the medical establishment to inform his/her consent is complete and exhaustive with regards to the physical or psychological risks involved in this act. Finally, it was suggested by the Committee that, with a similar treatment also for the other kidney donations from a living donor, this act of generosity is taken into consideration, in order to translate it into a criterion of preference in the waiting lists, should the donor him/herself need a kidney.

Since 1999, with the Law n. 483 of the same year, it's possible to transplant a portion of the liver and since 2012 it is also allowed partial transplantation between living people of lung, pancreas and intestine (Law 19 September 2012 n. 167); Even in these cases will be applicable the same provisions as far as compatible.

5. Definition and certification of death

The definition and certification of death is regulated by Law 578/1993 and Ministerial Decree no. 136 of 11 April 2008, according to which death coincides with the total and irreversible cessation of all functions of the brain. This can be certified with:

- Neurological criteria: for a period of not less than 6 hours, accurate clinical and instrumental tests are carried out to establish the simultaneous presence of the following conditions: state of unconsciousness, absence of reflexes of the trunk and spontaneous breathing, cerebral electric silence
- Cardiac criteria: an electrocardiogram is performed for a period of not less than 20 minutes. This is considered the time of anoxia, after which there is certainly an irreversible loss of brain functions and therefore the death of the individual.

Both these criteria have caused in the last few decades widespread scientific and ethical debate, also in consideration of the advancement of medical knowledge.

Donation after encephalic death is now worldwide accepted and the majority of the transplants take place in this case. However, the enormous time that elapses for the patients in waiting list because of the lack of organs brought to consider further the Non-heart-beating organ donation. This type can be defined as *donation of organs and/ or tissues from deceased patients with irreversible cessation of cardiac function*. The heart has ceased beating, and this event cannot, or will not be reversed.

The Italian National Bioethics Committee tackled the problem of the criteria used to declare human death and it considered in the opinion released in 2010 that the circulatory criterion is clinically and ethically valuable as well as the neurological criterion.

In this opinion the National Bioethics Committee intentionally kept the problem of ascertaining death separate from that of organ transplants, in order to give a definition of death which must be objective and not be influenced by any kind of purpose. The certification of death has to be an independent status from the eventual removal of organs and from any utilitarian consideration relative to the social-healthcare costs.

However, the Committee was conscious of the link between and that organ transplants must be taken into account especially when the issue is seen in a practical perspective.

The adopted criteria must also fulfil the condition of rigorously and meticulously respecting the clinical pre-requisites of the methodology, the procedures and the eventual use of verification tests. For this reason, we recommend the highest possible uniformity in the protocols, both with regards to the cardio-pulmonary and the neurological criteria, which at the moment seem often different from country to country, causing confusion in public opinion with negative effects on the relative belief in the reliability of the criteria themselves.

In particular, the time to ascertain death by cardiac criterion is the point in which there is more debate. In fact, while in other countries the time requested to ascertain death could be very short (2 – 5 minutes), in Italy is established that death can be declared only after 20 minutes of flat electrocardiogram⁵. Although the Committee considers that the generally established time elapsed from the cardiac arrest is too short and insufficient

⁵ Decree of the Ministry of Health n. 582/1994, art. 1: In accordance with art. 2, paragraph 1, of the law 29 December 1993, n.578, the ascertainment of death for cardiac arrest can be carried out by a doctor with the continuous graphic survey of the electrocardiogram extended for no less than 20 minutes early.

to declare the irreversible loss of encephalic function and because of this the patient may still be alive, it considers that 20 minutes

In particular, the NBC's criticism towards the definition of death by cardiopulmonary criteria, focuses on those protocols, found in other countries, that establish very short times (between 2/5 minutes) to ascertain death. The risk is that the patient could still "be alive", as the extremely short time elapsed from the cardiac arrest is insufficient to declare the irreversible loss of encephalic functions.

Finally, the National Bioethics Committee recognised that Italian legislation on ascertaining death, supported by current guidelines, is extremely protective and prudent and has allowed medical institutions to adopt homogeneous practices. However, it recommended to be always open to further analysis of the problem, especially when new or previously overlooked scientific data emerge.

6. Italian Legislation on Transplantation of organs by a deceased donor

The Italian legislation protects in a very clear manner the figure of the donor, starting from the full respect of the will recorded or expressed in life in the manner in force; in the event that the person has not issued a statement on the subject, the donation of organs and tissues can only take place if the family members do not oppose.

Among the main guarantees provided by our legal system is the total independence between the process of death assessment, a necessary condition for the removal of organs and tissues, and the possible donation. In fact, if the clinical conditions to ascertain the death of a person with neurological criteria or with cardiac criteria occur, doctors have the duty to proceed with this procedure, regardless of the possible donation.

In addition, the Committee of Medical Experts that certifies death is independent of who has found the state of death and different from the team that will perform the collection and transplantation. This commission, consisting of an anaesthesiologist, a neuropath physiologist and a medical examiner, is convened by the Health Department of the hospital facility where the person is located.

Every adult citizen can express his consent or dissent aimed at the donation of organs and tissues after death through one of the following ways:

- signing the form at your local health agency (ASL) of reference
 1. module ASL Italian
 2. module ASL German
- at the registry offices of the Municipalities at the time of issue or renewal of the identity card (in this video more information)
- filling in the blue card of the Ministry of Health or one of the Donor cards distributed by trade associations; in this case it is necessary to keep this card among your personal documents
- compiling the holograph of the Italian Associations for the donation of organs, tissues and cells (AIDO)
- reporting your will on a blank sheet, including date and signature; also in this case it is necessary to keep this declaration among your personal documents

These ways are all fully valid under the law. The declaration made to the ASL, the City Council and AIDO is registered in the Transplant Information System and can be consulted by doctors to verify, if necessary, the existence of an expression of will on donation.

All citizens assisted by the National Health Service and who have been assessed clinically suitable for transplantation by the center where they have decided to care can be registered on the waiting list.

Waiting lists in the area of organ transplantation are unavoidable, since the demand is greater than the supply of organs available; for this reason, even if it is possible to intervene with organizational actions, To reduce waiting times, it is necessary to increase consensus and reduce opposition to donation.

The suitability of a patient to receive a transplant is assessed on the basis of national indications shared by transplant centres. The number of registrations allowed to each individual patient may vary depending on the transplant program that the patient wants to access. For kidney transplantation it is possible to register in two different lists (one in the region of residence, the second in free choice), for the other types of transplantation (liver, heart, lung, pancreas) only one entry is allowed in one of the transplant centres in the national territory.

Different is the case of pediatric patients, who, being in a smaller number, are registered in a single waiting list (pediatric program) managed nationally by the National Transplant Center, which also proceeds to the allocation of organs to small patients.

In addition to the paediatric programme, the CNT also runs other organ allocation programmes, including the emergency programme (dedicated to patients in grave danger of life), the one dedicated to hyperimmune patients, that is, those patients who, due to a high immune response, have more difficulty in being transplanted, in addition to the management of all those organs that, procured by a Region, do not find a recipient in the same Region of the donor and, for this, are defined "surplus".

Organs are assigned on the basis of an algorithm that reflects several parameters: the severity of the disease for which the transplant is needed, compatibility, blood type, age and waiting time on the list. This allows the

most suitable organ for the patient to be assigned with rigorous and transparent procedures.

Trafficking on Human Body

The need for organ transplants has increased, in recent times, also in reference to the progress of medicine, exponentially. However, the increase in demand is not matched by an equally equal supply, given that, in any case, it must follow the legally institutionalized process. We are thus witnessing the phenomenon of illegal trafficking in organs as a living being, where the donor is identified as being in poverty, generally in the Third World, who, in order to survive, offer the removal of one's own body after payment of a sum of money. Not only that: this traffic takes place through brokers, very often even members of criminal associations, who retain a large share of the price charged to the user.

In short, trafficking in human organs as a living has given rise to a kind of international trade and tourism dedicated to this purpose, constituting a form of real human trafficking, with a serious violation of human rights, of his dignity and physical integrity.⁶

The Law n. 236/2016 introduced into the penal code the crime of trafficking of organs taken from a living person. Inserting in the criminal code a new article 601-bis the law:

- punishes the illicit trade in organs, providing for imprisonment from 3 to 12 years and a fine of 50,000 to 300,000 euros for anyone who illicitly trades, sells, purchases or, in any way or for any reason, procure or process organs or parts of organs taken from a living person. If the author of the fact is a health professional, the sentence carries the

⁶ Pittaro, 2017

accessory penalty of perpetual prohibition from the exercise of the profession. The precondition for the application of the criminal case is that the organs are treated unlawfully. The provision is therefore intended to be applied in the event of a breach of the rules on transplantation of organs and tissues taken from living organisms currently in force;

- punishes with imprisonment from 3 to 7 years and the fine from 50,000 to 300,000 euros the two different conduct of organization or propaganda of travel aimed at the trafficking of organs and advertising or dissemination by any means (including by computer or telematic) advertisements for such traffic.

The size of the penalties allows the application of Italian law even when the facts are committed abroad.

In addition, the law has modified the crime of conspiracy for criminal, provided for by art. 416 of the criminal code, to provide that it is aggravated when the association is aimed at committing crimes of trafficking in organs taken from a living person, trafficking in organs from corpses and mediation for profit in the donation of organs from a living person. The aggravated crime involves the application of the penalty of imprisonment from 5 to 15 years or from 4 to 9 years, depending on whether it is the activity of promotion, constitution or organization of the criminal association, or simply take part.

Finally, the law has provided for some coordination provisions with the legislation on organ transplantation already in force. In particular:

- intervenes on the law on transplants (Law n. 91 of 1999) raising the prison sentence provided for mediation, for profit, in the donation of organs from living, bringing it to a maximum of 8 years of imprisonment (instead of the previous 6);

- repeals Article 7 of Law No. 458 of 1967, on transplantation of the kidney between living persons. This is the provision that punishes with imprisonment from 3 months to a year and with a fine from 154 to 3,098 euros anyone, for profit, performs mediation in the donation of a kidney.

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