“HUMAN TRANSPLANTATION: THE ITALIAN LEGISLATION”

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abstract: lungo una decina di righe, in inglese, corpo 10 chiaro, Times New Roman, giustificato, rientrato di 0,75 cm a destra e a sinistra, interlinea singola.

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ACADEMIC YEAR
2016/2017

STUDENT ID
077472

General Index

AKNOWLEDGEMENTS

To my parents, Daniela e Renato, who are the most important persons of my life and who have been there all the steps of the way, I couldn't make it without you.

To my grandfather, I love him unconditionally since I was born.

To Guglielmo, who makes me happy every day and whose love has encouraged me to never give up.

To Flaminia, who is a friend, and it is not so easy to be.

CHAPTER 1 -INTRODUCTION
ORGANS TRANSPLANTS AND THE FOLLOWING PROBLEMS

In our society it is possible to make a gift: the organs donation. People can deliberately decide to allow that organs and tissues will be taken to be transplanted to patients in the waiting lists.

The purpose of this thesis is to analyze how this process is regulated in Italy. The way by which is possible to do that is the analysis of the law n.91, 1999, the one which regulates that issue. It is for this reason that this document has a legal character. Anyway, the aim is not just to examine the n.91 law text and interpret it, but to try to point out all the incongruences on the transplantation that are present in our legal system.

The thesis is written seeking to use both objective definition (about the transplant for example) and objective facts (news or newspapers articles), but also to study this issue from a moral point of view, taking into consideration the bioethical principles and point of views, without forgetting the traditional habits, which could have had influenced the legislation process, or at least the grade of Italian predisposition towards transplants. About the law n.91, the approach is not a technical and specifically legal one, in fact the goal is to make it understandable, in order of being able to critically comment it, reporting the legislative text "in other words", but also documenting opinions and investigative reports about it, and comparing the Italian model with other legislative models of different countries. Doing all to take conclusions and make questions about the rightfulness of that Italian law.

The document starts in this first chapter with the introduction of the topic "transplants", explaining when and how it is possible to make them, and proceeds presenting the national and international problem produced by the organ transplantation: the scarcity of organs.

Continuing with the focus of this thesis, the Italian case, in the second chapter. Firstly, there is a brief history of the development of the Italian transplants law until the law n.99, 1999, then there is the explanation of that last law and its implications, followed by the stress on the tacit consent principle, a principle introduced by the law n.91. Then, there are the paragraphs on the main aim of this thesis: to highlight the problems of the law n.91 (ex. Art 5, the never written decree,..). Only after having done an accurate analysis of the Italian situation it is presented the situation of others countries, to make a comparison.

Finally, in the third chapter, there are the considerations, which are the results of the critical analysis that I have tried to do: "Can the tacit consent being considered an illiberal principle?"; "What do we owe to others?"; Is the tacit consent an utopian law?".

1.1. Definition of transplant and verification of death

First of all: What is transplantation?

Transplantation is a surgery that involves replacing an organ or tissue with another one taken from the same individual, another individual (transplantation) or an individual of different species (xenotransplantation).

We can identify two steps:

1-the withdrawal of the part from a donor subject,

2- the subsequent transplantation or graft of the subject on the recipient, with the possibility to remove the sick organ.

The entire organ can be transplanted (kidney, liver, heart, lung, intestine), a part of them (liver, who is capable to regrow itself), tissues (cornea, bone, cartilage, heart valve, blood vessels, cute), or complex sets (hand).

Bioethics affirms seven principles about organs transplantation[1]:

1. Respect of life as an unavailable value
2. Safeguard of the identity of a person and of his/her descendant
3. Nature of experimentation – organs transplantation can be accepted at the condition that it is the one and only valid remedy and that it has high probability of success.
4. Solidarity
5. Costs/benefits proportionality

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[1] Organs transplant, fundamental principles of bioethics, online article: http://www.bioetica.itst.it/pls/itst/v3_s2ew_consultazione.mostra_paginat?id_pagina=112&target=0

6. Informed consent
7. Verification of donator’s death

1.1.2 Definition of death

It is interesting to focus on the seventh point: the organs can be taken by a deceased person when the law has established his death. In the past, death was defined as the end of the cardiac activity. In the 1959 the French specialists Mollaret and Goulon introduced the term “coma depassè”, to define the status in which there is the irreversible cessation of all brain functions but the possibility to sustain artificially the earth functions. In the 1980 the President of the Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published the document “Uniform Determination of Death Act” (UDDA) with the purpose to uniform the definition of death: “An individual who has been subjected to the irreversible cessation of all brain or of the respiratory or circulatory functions is dead.”[2]

In Italy the concept of death was established by the law n. 578 (1993), which in the art. 1 and 2 states: «Death is the cessation of all brain functions». In addition to that law there are two decrees: 2 August 1994 n.582 and 11 April 2008. -The encephalitic death must not be confused with the coma or the vegetative state, both these states relate to a living person-After the verification of death, the following step is to establish biocompatibility of the organ between the donor and the recipient. If the compatibility is ascertained it is possible to proceed with the explant. Then, organs are cooled waiting to be implanted. The main criterion to match donor and recipient is compatibility but the choice is also influenced by others factors such as age and health of the patient who is going to receive the organ.

1.2 Organ transplants: problems

The real problem is that the mortality among the waiting lists of patients is high, due to the insufficient number of organs available for the transplantations. It is unbelievable that still in 2016 there are news such as

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[2] Uniform Law Commission. Uniform Determination of Death Act. Official website: http://www.uniformlaws.org/ActSummary.aspx?title=Determination%20of%20Death%20Act

«5 years old children died, lacking a donator» (Il Mattino, 2016 Padova)[3]. Two or three years to operate all the patients in waiting lists, this is the time estimated in 2016 by the 40th Congress of Italian Society of Organ Transplants. The experts affirm that Italy is a two speed country: where innovations and professionalism are fast, instead the consciences are not. The quality of transplant centers is high, but the number of transplants done is too low, and this is due to the lack of donation culture. Moreover, the scarcity of organs limits the diffusion of Transplantation Centers. Today, the shortage of organs is no longer a national problem, it has become an universal issue. In some developing countries, it is impossible to develop a defunct organ donation program because any effort is blocked by social, cultural, religious, legal and other factors. The situation is not different in developed countries, where rates of deceased organs' donation are likely to be even higher than in other countries, where organs from expired people cannot provide for the increasing demand. The current increase in cardio-metabolic diseases and the aging populations are leading to an increase in the problem of kidney disease and so to the need of setting social and ethical challenges. During the 1990s the number of patients with end-stage kidney disease (ESKF), those requiring a dialysis therapy or transplant, in the United States increased and almost doubled, going up from 196,000 in 1991 to 382,000 in 2000. It would be enough to solve the kidney shortage even just if one of every 3,000 people became a kidney donor. Furthermore, 94 per cent is the one-year survival with a deceased-donor kidney, 98 per cent with a living-donor kidney. Because of this shortage have been advanced more extreme proposals such as to recover organs by supposed consent and to prepare a market plan aimed to reward donors that can complement voluntarism. Then, too, animal organs, organs grown from stem cells, or artificial devices might ultimately eliminate or severely reduce the need for organ donors.

1.3 Black market

Anyhow, until today, the living donors are the shortage remedy most practiced, but the sale of transplant organs from non-deceased donors are unlawful in many countries. In the west, the first aim is to protect the interests of the donor in light of the Hippocratic oath, *primum non nocere* or 'first do no harm'. Paid donation does not sustain this affirmation, it is

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[3] Il Mattino, Padova. Online newspaper. URL: http://mattinopadova.gelocal.it/padova/cronaca/2016/02/03/news/niente-trapianto-muore-a-5-anni-1.12889606

considered unethical. Many people in the west, failing to find an available organ, have started to seek transplants overseas, often in developing countries. The 2008 Philippines' legislation, aimed at preventing the country from turning into «the kidney capital of the world», is the proof of this phenomenon. Frequently these individuals seeking an organ do not ask questions about the provenience of it. Dishonest health professionals who see the potentiality of money benefit and exploit disadvantaged recipients and vulnerable sellers, believing that their sole ethical duty is to protect donor interests, carry on those surgeries. The black market of organs is a real problem and the worse is that often it is the solution of families who have tried the legal way, but are constrained by the too long waiting lists to choose the illegal one to escape death. The only real and efficient solution that today has been verified is the diffusion of the "gifts culture". Different associations are being constituted in order to encourage people to donation, advertising campaigns on television have been introduced and, especially, the institutions are trying to diffuse as much as possible culture and information about this topic.

CHAPTER2 ORGAN TRANSPLANTS IN ITALY

2.1 History

In Italy the donation system has been regulated by a set of European directives, of law and national decrees, of guidelines and protocols, which guarantee quality, traceability, and transparency in the processes. The Health Ministry has made available to citizens the whole normative regarding the donation process, explant and transplantation, which can be consulted via web. [4]

The Italian legislative process regarding organs' explant has started in the 1957. A climate of skepticism was diffused because of cultural and religious motivations, in the belief that surgeries on a dead body could violate the respect towards the defunct. So it was a long process, but at the end the legislations of that period have progressively affirmed the organs explant as a cornerstone of human solidarity. Anyway this topic is not easy, various legislative adaptations have been made. On the 2nd December 1975 law n.644 gave a first normative regulation on the explant from a dead body and on the debated definition of death. In the 1993 was redefined the concept of death as a brain death, halving the term for the verification (from 12 to 6 hours), except for children. In the following years different laws have been promulgated about the organization and execution of transplants, but only in the 1999 it was defined a law which has represented a turning point.[3]

2.2 Law n. 91

This law is the law n.91 (1st April 1999): «Disposition about explant and transplantations of organs and tissues». It can be divided in five fundamental points:

1. National organization of the system of explants and transplantations organized in: CNT (National Center of Transplants), CIR (Inter-regional Transplantation Centers), CRT (Regional Centers for Transplantations), CL (Local Coordinators), structures for explants, structures for the conservation of tissues explanted, structure for transplantations.

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[4] Health Ministry. Transplants, official website of the National Transplants Center. URL: http://www.trapianti.salute.gov.it/cnt/cntLineeGuida.jsp?id=35&area=cntgenerale&menu=menuPrincipale&sotmenu=normativa&label=norm

2. Declaration of the citizen’s will about the explants of organs and tissues
3. Institution of the role of the local coordinator
4. Formation of the professional figures involved
5. Institution of the SIT (Informative System of Transplantation)

1- CNT is a structure, which has the role to control, verify and manage clinical and pediatric urgencies, and release the guidelines and the operative protocols for the explant and transplantation activities. Monitoring, through the SIT (Informative System of Transplantation) the explant, transplantation made in national territory, waiting lists, will declaration of citizens and qualitative results. Moreover it is in charge to form the qualified body and to promote information.

   CIR: traditionally there were three organizations AIRT (Inter-regional Transplantations’ Association), NITP (North Italy Transplantation program), OCST (Center-South Transplantation Organization). In order to simplify and optimize the process of donation/transplantation, today these three organizations have flowed into the Operative National Transplantation Center.

   CRT is a structure with operative function for the management of transplantation/explant and for the location of organs at regional level

   CLs are the main actors of the potential donors identification phase. They are in charge to maintain ties with the donator’s family.

   The CNT together with the CNTO and CRT lead to an increase of the donators’ number and consequentially to the transplantations’ number.

2- The citizen declaration about the will to donate organs.

   It is regulated by art. 4 of the law n. 91/99, which introduce the principle of tacit consent: «citizens have to declare their free willingness about the organs and tissues post-mortem donation and are informed that the lack of will declaration would be considered as a consent to the donation».

   Every adult citizen has the possibility, but not the obligation, to declare his/her consent about post mortem donation or deny it through the following ways:

   -A written declaration, which the citizen brings with him.

The 8 April 2000 ministerial decree has established that each written note that includes first name, name, birth date, will declaration, number of ID, date and signature can be considered valid.

-The registration of the will at the reference ASL or the family doctor through a specific module. Declarations are registered in the SIT (Informative Transplantations System).

-The sign up of one's own will at the General Register Offices, which have activated the system at the moment of the release or renewal of the ID.

-The compilation of the blue card received by the Health Ministry, which has to be taken together with the ID.

-The holograph document or the AIDO (or other volunteer associations) card.

-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.

3- Local Coordinator

Art 39: The nurse assists the family of the patient, particularly in the end of the illness and in the grief elaboration. Art. 40: The nurse promotes information and education about blood, tissues, organs donation as solidarity acts and assists donators and recipients. In Italy**,** the Local Coordinator has the role to explant and he/she can use coworkers, which usually are nurses. In fact nurses have a fundamental role in the education about and diffusion of donation practice. He/ she is very close to the patient and his family and has the knowledge and capability to encourage and inform them.

4- Formation of professional actors

The Health Ministry together with the University and Research Ministry, institutes scholarships aimed to the formation either of explant structure and of the staff who has to take care of donators and recipients.

Regional structures are given the role of promoting the update and upgrade of healthcare professionals.

5- The Informative System of Transplants (SIT) within the National Health Information System has been established for the collection, in a single database, of willingness about donations of organs and tissues. With regard to receivers, waiting lists are managed at regional level. The SIT is connected to the Regional Transplant Centers and Local Health Professionals, which, according to the quoted ministerial decree of 2000, play the role of collecting points of citizens' wishes and transmission, in telematics mode, of their data to the SIT. The SIT is interconnected with the database containing the holographic testaments of the AIDO associates, which are made available in real time: by 2013, more than 1,230,000 collections accrued, against 141,000 statements via Healthcare Professionals, with a first legitimacy of "biological will". From 2013, it is possible, in some cities, to subscribe to the SIT also through the Registry Office.
For life-threatening organs, in emergency patients, the transplant progression should be followed over time based on a common national protocol defined by the National Transplant Center. The data must be collected in a national register.

Legislation has also been updated over time to transpose the EU Guidelines on donor selection, quality and safety of organs and their transportation; There are still no Directives that harmonize management of waiting lists and allocation criterion.

DONATORS 1999 – 2016 (per millions of population)[5]

1999	2010	2016
788	1.095	1.298
13,7	18,2	21,4

2.3 Limits on organs donation

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[5] A.I.D.O. Statistic data, official website: http://www.aido.it/dati_statistici/trapianti.htm

The Italian legislation sets there limits on organ donation.
The first two are that it is not possible to explant gonads and brain. Comma 3 art 3 law 01/04/99 n.91. This prohibition is due to the principle of cadaver’s safeguard as a protection of human person and as expression of the personal principle, which is a cornerstone of our legislation.

2.3.1 Gonads

The gonads transplantation would threat the biological and psychological identity of the son who will born from the recipient, because the unborn will be procreated with a gamete originated by the parent, but with a genetic heritage of a third defunct person. Moreover the gonads transplantation cannot be considered useful because it would not save the life of the patient, it would just solve the “fertility problem” in the case in which the recipient is unfertile, so it would exceed the limits allowed by the law.

2.3.2 Brain

About the prohibition of explant of brain, if it is true that law n. 91, 1999 affirms the explant from who is brain dead, it is useless to deny the explant of an organ which is already dead and consequently cannot be given.[6]

2.3.3 Embryo manipulation

The third ban is about the embryo manipulation with the aim to obtain compatibility between the unborn and a third person, who is a potential beneficiary of transplant.

2.4 Tissue from an abortion

Another possible issue could be the possibility to use the biological tissue from an abort, but this in Italy is still not a debated issue from a legislative point of view. In the law n. 194 art 6, 22 May 1978 is not included the option to abort with the only aim to use the fetus tissue. In the United States and in Sweden, it has been successfully practiced the transplant from fetus

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[6] Cicognani A, “Mors tua vita mea” verification of death and biological organs and tissues transplants, Italian Jurisprudence, 1994

tissues to adult tissues for the purpose to vanquish diseases such as the Parkinson and the Alzheimer. American legislation states that, with previous consensus from the dead mother, there is no reason to prohibit that fetus tissue should be used for a beneficial scope.

In Italy this is not allowed, it is unacceptable because of its ethic profile. «It is not possible to use a living person and take some pieces of its body to help another person or save his life». (Pope Wojtila). The use of human embryos violates the natural biological procreation.

The opinion of Pope Wojtila is relevant in this case, even if legislation is not a church's matter, because Catholic church in Italy is very influent. It defends the inadmissibility of transplant from living person, even if the organs are reproducible. Pope John Paul II recognized that transplants are a big conquest from a scientific point of view and stated that it is appreciable the donation of organs to help sick people, but only post mortem.[7]

2.5 Respect for the cadaver

As a dead body is referred to as: any inanimate body or a being who was never alive, a dead born person. The penal code guarantees not the cadaver itself but the feelings of respect and veneration towards the body. The rights of physical and psychic integrity are included into the inviolable rights, instead the rights to have at one's disposal his own cadaver is not. Our legislation tutelages the dignity of our dead body not because they have been alive but because pietas towards the family of the deceased should be conceded. The funeral rite is an important phase for the elaboration of the death, a way to escape the pain.

In several countries, legislations give to the families the right to decide whether to donate or not the organs of their dead relatives, but this is not the case in Italy, where with the n.91 law 1999 the traditional preeminence of the parents will on the defunct will was abolished. The donation of organs can be considered part of the solidarity principle, nevertheless, the State recognizes to the citizen the possibility to deny the donation of his own body, donation that would be coherent with the solidarity principle. It seems like a compromise in order to respect the cultural and religious belief, profoundly eradicated in the Italian tradition. Today, the more suited solution is the possibility to manifest our own dissent, in absence of which the citizen is considered tacitly consentient. Undoubtedly, in case of a

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[7] *(*Encyclical letter Evangelicum vitae)

conflict between the duty of solidarity and the rights of parents to have the respect of the body of the dead relative and the rights of tutelage of life and physical integrity of a living will, the second ones will prevail. The art 7 of law 644, 1975 confirms the respect of the dignity of the cadaver, which imposes the denial of unnecessary mutilations and dissections, and the obligation of the reconstitution of the cadaver, even in the case of an autopsy.

The actual legislation denies the “organ office explant”, as they would be a public thing which, once the individual is dead would not be anymore his ownership but would be ownership of the community. So it has been established to increment the “gift culture”. This means to plan consistent investments in the diffusion of information and formation of subjects in order to sensitize the public opinion. In fact there is a general diffused indifference and ignorance about the concrete use of what the humanity would do of the scientific progress if only we allow it to grow. Information can be a useful way to eliminate the cultural and religious beliefs that are consistent obstacles.

2.6 Scarcity of organs

Organ scarcity, caused by donation scarcity, can be related to two main causes: firstly, the disinformation about the importance of the verification of the brain death. In fact it is not clear that clinical death and biological death are identical, even if defined in different terms; secondly, the lack of clarity about the norms for the consent of the explant. The law of 3 April 1957 n.235 states «it is allowed the explant of dead body part for a therapeutic explant if the subject has given the authorization. Lacking direct dispositions, the explant is allowed if there are no oppositions from the spouse or the relatives by the second degree of kinship». In the article 6 of the law n. 644 of 1975 it is affirmed the right to opposition to the explant and so the lack of opposition while an individual is alive would be considered according to the principle of tacit consent. Anyway, this implicit consent would have been subordinated to the familiars’ right, to which (ex article 6) was leaved the right to decide about the cadaver. Thus, there are two opposing rights: the one of the living person, and the one of the family of the dead person who has to show at the hospital the written opposition. (art 6 legislative decree n. 409, 1977: «the health worker has to inform the involved familiars that the lack of a written opposition by the explant times, would lead to the explant»). Through the over sixteen citizens registration to the ASL, anyone who would decide not to take a written opinion against the explant would be considered a donator. This is the consequence of the emergency to find a solution to organs scarcity. It was with the aim to inform the Italian citizen in order that he would have been able to consciously decide for himself that was emanated the law n. of 1 April 1999. It have been reunited the law project n.3646 “Norms for the will manifestations for the organs and tissues transplant” and the law n. 4100 “Norms on the organization for organs and tissues explants and transplants from dead bodies”. This new law, as we have seen, is focused on the diffusion of transplant culture, the regulation of will declaration for the organs and tissues explant and the general organization of transplants. Statistics and surveys show that the donators’ scarcity is a common problem, but in Italy the responsibility for the scarcity of available material and of the excessively long waiting lists, it is due to a bad legislative regulation and a deficient organization of public health structures.

2.7 Lawfulness of explant

In the present law 91/99 articles 4 and 5 discipline the will declaration about the organ donation. Art 4: «citizens have to declare their free will on the organ and tissue donation, after their death, and are informed that their omitted will declaration it is considered as a consent to donation». It is so established the necessity to ask to any donator to declare his own dissent to the explant. In the art 4 there is a part about the lawfulness of the explant. Two different systems can be assumed: the first one justifies the, partial, explant according to the concrete social utility of the substitutive surgery which can save human lives and so based on an interest preeminent on the individual one (nationalization of cadavers). The second one, is the private one, by which is given a predominant role to the individualistic will, the will of the defunct and of his family. With law n.91/1999 a solution was reached, an equilibrium point between the solidarity principle and the free will, in which we can find the tacit consent principle, calling the citizen to exercise the duty-right to declare his will, giving the most important role to the autonomous choice. So there will be donators, non-donators, and presumed donator, who are donators according to the tacit consent principle. Consequently the human body, without the majority knowing, has turned into an exclusive property of the Italian institutional authority, which assumed the right to use it.

2.8 Consequences of the tacit consent

In the 1995 Martin Branch, a young Dutch tourist who was spending his holiday in Italy, was knocked down by a car. Hospitalized in Naples, the doctors planned the organ explant, but before starting they informed the parents. Fortunately the parents denied the transplant, because after a while Martin woke up from the coma. Another example can be the scandal in Liverpool at the Harley Hey in 2000, when were discovered 8000 dead children to whom thousands of organs had been explanted without the parents awareness and preserved in the hospital canteen for the purpose of research.[8]

Anyway, after numerous scandals, related to the tacit consent principle, different limits have been established: today it is provided that this principle has to be enforced only as emergency measure, in the cases in which the patient had received the notification to express his will but he had not done it. Moreover, with the request of the individual, the opinion of the family can be invalidated, who today can only have the role of witness or interprets of a will previously expressed. Therefore, the turning point could be the exclusion of the relatives.

2.9 Art 5

The problem is that the validity of this principle would fail as, inefficiencies and an excessive bureaucracy would make difficult the registration of each will declaration. Consequently, article 5 of the above-mentioned law is of great importance. The tacit consent mechanism is articulated in the following different phases: the first, in which the local health companies have to notify to every citizen the formal request to express their will, advising that missed declaration would lead to the tacit consent and making periodical reminders; the second is about the registration of the will either by the scheduling of the health documents of the interested and, by the Informative System of the National Center. Article 5, comma 3 is about children (under 18), providing that the will has to be expressed by the parents, who necessarily have to agree with each other. Contrarily, no substitutive declaration for unborn children, the incapables and the ones who are given in custody of assistance structure is provided.

2.9.1 Problems with art 5

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[8] Gianni Lannes. Bambini a perdere. Scomparse, violenze e mercato dei corpi. Ed. Luigi Pellegrini, 2016

The problem is that in the light of the described mechanism if it is correct that the information is unavoidable, it would not be to possible to proceed with the explant from a dead person, also if that person was an activist of a donators association, who had expressed his consent, if, for an administrative error of the ASL, has not been notified the request of will manifestation. When there is a missed notification nothing would be valid to transform a non-donator to a donator, neither a will declaration expressed according to the law form. It sounds controversial also the fact that before 18 years of age, there is no possibility to take a position against the organs transplantation and so to decide for one's own body accordingly to cultural and religious beliefs that can already be formed and so would have to be respected.

2.9.2 The never written decree

On the basis of art 5 was given to the Ministerial decree the determination of the way to put it in to practice all the regulations of the law n.91 mentioned above and in the transition phase, waiting for the decree, it was considered possible the explant if the defunct had not expressed a dissent, instead the family opposition was possible, unless the defunct had expressed the consent. The person who wanted to express his will on the transplant would have had the possibility filling the card, which was distributed with the certifications of the May 2000 referendum or in a written paper, as long as signed. With the actualization of the law firstly, it would have had to be predisposed an informative campaign, followed by a delivery of a module to be filled out and to be sent, within ninety days, to the ASL, which would had sent them to the informatics center, that could be consulted to discover the identity of the donors. The law provided also the institution of a Nation Transplants Centre and of Permanent Technical Council and a Local Coordinator.

However, the major controversy of the Italian legislation is that the most innovative component of the law n.91, 1999, the tacit- informed -consent («we are all donators, unless we deny that while we are alive») published in the "Gazzetta Ufficiale" on the 15th of the same year, has never been applied. As an article of the "Fatto Quotidiano" shows, the principle is written, but a decree would be necessary to start with the notifications. This decree has never been written and the Health Ministry does not answer to the question "Why?". After eighteen years from the emanation of law n.91, article 23 is still in practice, although it should have been merely provisory.

The worst thing is that article 23 refers to the comma 3 of article 28, which in turn goes back to article 7, which describes the organizational principle for explants and transplants of organs and tissues. When the law was approved, the Health Minister, Mrs. Rosy Bindi, said that it was «an important result», a law thanks to which we were able to enter in Europe, where this principle was diffused since 1983. However it cannot be considered a turning point since the principle has been legislated by law, but it has been preferred not to apply it. The problem is about the actualization of art 4 («The citizens have to declare their free will about the donation of organs and tissues of their own body after the death, and are informed that the missed declaration of will is considered as a tacit consent»), because the terms, forms and procedures through which the local health authority has to notify their citizens, should have been instituted by the above mentioned never-written decree. The data should have been collected by the SIT, for which one billion liras were allocated. It is not really the present reality.

2.9.3 Present situation

Today, it is the SIT that collects the will declarations from the ASL, AIDO, or the Municipalities that join the project “A common choice”. Umbria started as the first region in 2012 and then the project was opened to the others. In practice the local administrations can decide to collect the declarations of will when they emit the Identity Card. It is only necessary a deliberation of the *giunta* and an interconnection between the Municipality and the SIT, an option that was present in law n.91. The subscription is not compulsory. While in the Bolzano province 89,7% of the centers join the project, 9.51% in Abruzzo, in Basilicata 5,43%, Campania 4,73%, Calabria 4,65%, Molise 4,41%. This can be explained by the insufficient health assistance in the South. The most surprising data is that in Italy there are 24,3 donators for millions of population, in Calabria 11,6, in Tuscany 53 (!). If every region had the numbers of donation of Tuscany, the problem of the waiting lists could be solved, beyond the law.

2.10 Other controversies

2.10.1 art 8

Moreover, according to art 8 (comma 6 letter c) of this law, it seems that control functions and the definition of criteria for the insertion of people in the waiting lists are given to the CNT, but this seems in contrast with what is prescribed by the letter f of comma 6 art 8, in which is affirmed that the

CNT «proceed to the assignation of organs for the urgent cases»: this direct intervention, actually, would be limited only to very particular patients.

2.10.2 Intensive care conflicting situations

It is also foreseeable that this law can create conflicting situations in the intensive care department. In fact, health assistants have the duty to verify death (law 578/93) and explant the organs whenever possible (law 644/75 and law198/90). A family's opposition, in case of an unexpressed willingness of the defunct, even being informed, should be ignored by the health assistants, unless it is added to a signed declaration of the defunct, in order not to perform a crime of omission of acts of office.

2.10.3 Incompetent patient issue

Finally, it cannot be left unmentioned the omission of legislative references on the tutelage of the autonomy of the "incompetent" patient on the exercise of the health choice about his own body. It is not given relevance to precedent will declaration. Instead, both by the Convention on Human Rights and of Biomedicine and the Code of Deontological Medicine, has been given value to the will previously expressed by the patient to decide the clinical procedure, when the patient loses his capacity of autonomous decision. The former was approved in 19/11/1996 from the European Council, art 9 states: «the desires previously expressed on a medical surgery by a patient, who at the moment of the surgery is not able to declare his will, has to be taken into consideration»; the latter states in art 34: «The doctor, if the patient is not able to express his will in case of life risk, cannot take into consideration what the patient has been declared before».

The resolution to all this controversies could be the introduction of clear and simple procedures in that decree that has still not been written.

2.11 Reaction of the public opinion

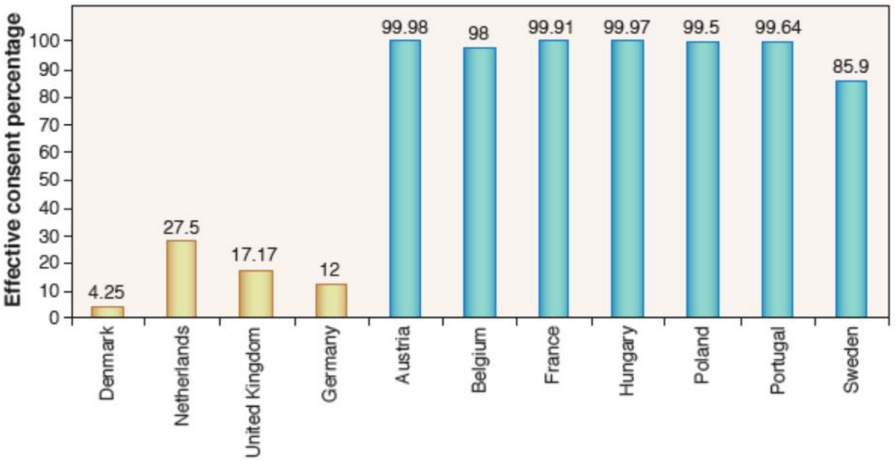
A positive aspect of this law is the credit to have given relevance to the information of citizens and health assistants, anyway, in the light of all this controversies, influenced by the Catholic Church and conditioned by cultural beliefs, the reaction of the public opinion about the approbation of the tacit consent principle could not be considered positive, as it can be seen from the titles of the major newspapers of those days (Corriere della Sera: «Transplants who keeps quiet, becomes a donator»; Il Manifesto: «Silence, there is transplant»). The astonishment is evident. Negative comments arrived also from doctors and representatives of AIDO. Enza Palermo, who at that time was the President of that association affirmed that «the decree doesn't seem suitable at all to satisfy the necessities of our country […], the legislative change seems worsening, because we passed from a situation in which all could be considered donators, to one in which, to be donators, it is necessary not only to express the favorable opinion but also have been informed by the Asl […]». In the newspaper "L'Unità" it is possible to find the opinion of Carlo Casciani, that at that time was the President of the Transplants Italian Society and the Director of the surgery clinic of Tor Vergata in Rome: «Article 4, Comma 7 states that the surgeon who does the explant can have two years of reclusion and two of exclusion from the professional activity, if he does not verify that the defunct has been informed by the Asl». Excessive bureaucracy and tacit consent were two of the major critiques.

2.12 Others European countries legislations

There are three different models about the personal consent of the donator:

1. Opposition rule: tacit consent, the organs and tissues explant is allowed if the defunct has not expressed dissent while alive. (Austria, Belgium, Spain)
2. Consent rule: express consent, explant is allowed only if the defunct has express his consent while alive. (Great Britain)
3. Information rule: if there is not consent or dissent the relatives of the defunct are informed on the possibility of the explant. (France, Germany, Sweden)

The Italian model is the one of tacit consent, which originate from a mix of these three models. What about other European countries?



Effective consent rates, by country. Explicit consent (opt-in, gold) and presumed consent (opt-out, blue).

In Austria we can find the tacit consent rule with the federal law n.273 of 1st June 1982. The same is for Belgium, Spain and France. In Belgium the law of 13th July 1986 states: «organs and tissues addressed to transplant can be explanted from the body of any Belgian citizen, except the case in which an opposition has been expressed». In France the law of 22nd December 1976, n.76-1181, in addition to the decree of 31st March 1978, n.78-501, art. 2 says: «can be made for therapeutic scientific scope, transplants from a person who had not expressed in life his opposition […]». Anyway in France, in practice, the *consenso latu* rule is generally applied, because lacking a declaration, the relatives are asked for their opinion and the explant is allowed if they agree. In Spain the law of 27 October 1979, n.30, art.5 states: «the explant of organs or other anatomic parts of the defunct will be made possible.. in the case in which the donator had not left an express declaration of his own opposition». The opposition rule should increase the organs available but this is not proven because the majority of countries that have adopted this rule, in practice adopt the rule of the consent in *senso lato*. In Great Britain the consent has to be written; in Germany in case of non-declaration it is allowed the consent of a relative; in Sweden, the consent must be written but, in absence of this, it is valid also the family's one.[9]

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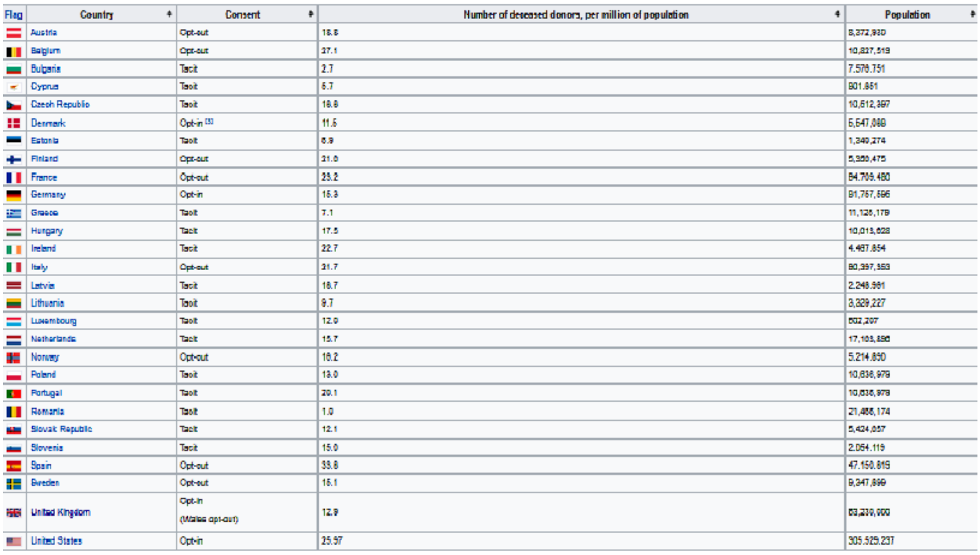
[9] Data on the URL: http://web.tiscali.it/scuolareginacoeli/genetica/leggi_tutela_donatori_%20e_riceventi/Legislazione%20in%20altri%20paesi.htm and

As it can be seen, there are differences between models adopted, but in most of the countries it is given relevance to the relatives' opinion. It is not correct to say that with the approval of the tacit consent Italy would have been part of Europe because in the other European countries it was already present. In fact in Great Britain, Holland, Germany and Sweden the consent has to be explicit, in other countries such as France and Greece the explicit consent is subjected to limitations and in the United States is necessary the explicit consent together with the relatives' consent.



Flag	Country	Consent	Number of deceased donors, per million of population	Population
	Austria	Opt-out	18.8	8,372,930
	Belgium	Opt-out	27.1	10,827,519
	Bulgaria	Tacit	2.7	7.576.751
	Cyprus	Tacit	6.7	801.851
	Czech Republic	Tacit	18.8	10,512,397
	Denmark	Opt-in [3]	11.5	5,547,088
	Estonia	Tacit	6.9	1,340,274
	Finland	Opt-out	21.0	5,350,475
	France	Opt-out	25.2	64.709.480
	Germany	Opt-in	15.3	81,757,595
	Greece	Tacit	7.1	11,125,179
	Hungary	Tacit	17.5	10,013,628
	Ireland	Tacit	22.7	4.487.854
	Italy	Opt-out	21.7	60,397,353
	Latvia	Tacit	18.7	2.248.961
	Lithuania	Tacit	9.7	3,329,227
	Luxembourg	Tacit	12.0	502,207
	Netherlands	Tacit	15.7	17,103,896
	Norway	Opt-out	18.2	5.214.890
	Poland	Tacit	13.0	10,836,979
	Portugal	Tacit	20.1	10,636,979
	Romania	Tacit	1.0	21,466,174
	Slovak Republic	Tacit	12.1	5,424,057
	Slovenia	Tacit	15.0	2.054.119
	Spain	Opt-out	33.8	47.150.819
	Sweden	Opt-out	15.1	9,347,899
	United Kingdom	Opt-in (Wales opt-out)	12.9	63,230,900
	United States	Opt-in	25.57	305.525.237

1Europe & USA summary- Organ Donor Designation in Europe compared to USA Wikipedia: https://en.wikipedia.org/wiki/International_organ_donor_rates

2.13 Sanctions in case of violation of tacit consent

Given that in Italy, at least theoretically, the tacit consent is in force, it is interesting to note the sanctions established in case of violation of that

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[9] ISS (Istituto Superiore di Sanità- Superior Health Institute) official website: http://www.iss.it/ecet/index.php?lang=1&id=100&tipo=2

principle. The article about this issue is the n. 22 and ratifies only administrative sanctions. It concerns:
-whoever does explant in non-authorized structures
-structures that omit to register data regarding the tissue conservation
-whoever does transplants in structures without reanimation departments

There are three alleged crimes. The first one is provided by art 4 comma 6, with the aim to tutelage the discipline about will declaration, so whoever will violate the precedent comma would be sanctioned with the ban from the health activity up to 2 years and with reclusion up to 2 years. The formulation of this disposition is of difficult understanding and vague, because possible violations have to be researched into the commas 2,3,4,5 of the same article.

In doing that, it is possible to affirm that it is illegal to explant organs or tissues from a defunct if:

It happens with an individual who had expressly said that he was against donation, who had given in time a signed declaration of its opposition and if the health worker would have been informed about the negative will;

It happens with a subject who had not received the notification from the Asl to obtain donation consent;

It happens with a child (under 18), when one of the two parents refuses to give his consent or with a child living in a health-assistance structure.

The other alleged crimes are about organs traffic and are stated in art 22 comma 3 and 4.

Comma 3 sanctions the explant made for profit-making business: “whoever picks up, for a profit-making business, an organ or a tissue, taken by a verified dead subject, will be punished with a reclusion from 2 to 5 years and with the fine from […] if the crime is done by a health worker, there will be also the never-ending interdiction to the exercise of the profession.”

Comma 4 regards the illegal explant: “there will be a punishment with reclusion up to 2 years to whoever takes, without profit-making business, an organ or a tissue explanted illegally. If the crime is committed by a health worker, there will be also the interdiction to the exercise of the profession up to a maximum of five years.

The only distinction between art 4 comma 6 and art 22 is that the former punishes the explant activity, the latter the procurement activity.

The established punishments have the aim of eliminating any traffic activity, avoiding that the missed proof of a profit-making business would lead to the absolution.

In all countries, it has been established the principle of gratuity, moreover our judicial system is based on the principle of equal opportunities between citizens, as expression of the supreme principle of equality, ratified by the Constitution, art 3. The problem is that the scarcity of organs encourages the illegal traffic, so it is necessary not only to establish a sanctioned ban but also to find out ways to increase the number of organs available.

2.14 Explants from pediatric and neonatal age children

It is important to mention the possibility of doing explants from pediatric age and neonatal age children.

The law n.578 of the 29 December 1993 established that the observation time for the death diagnosis, in children who are less than 5 years old, is duplicated, from 6 to 12 hours, compared to the one provided for an adult.

In children who have less than 1 year of age the period is even of 24 hours and to allow it, it is necessary that the newborn has been at least one week in the extra uterine phase and that he is born after at least 48 hours of gestation.

These provisions are aimed not only to guarantee the newborns but also to avoid phenomenon such as the conclusion of anencephalic pregnancy, in which the extra uterine survival is limited to few hours.

The anencephaly[10] is defined as a pathology that consists in the malformation of the neural tube, which happens between the 16th , and 20th month of gestation, in which there is the total or partial absence of the cranial vault and the above tissues. The total anencephaly makes impossible any vital function; the partial anencephaly is compatible with some expression of organic lives.

The first opinion about them sustains that they are something different because they lack the cerebral cortex and so they have a particular status, they are “living, but brain absent” and consequently it would be licit the organs’ explant even without death verification. This opinion would generate different problems. Whoever is in favor of this opinion believes that because an encephalitic individual has not the cerebral cortex where there are the nervous processes, which constitute our intellective capacities,

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[10] The terms anencephaly derives from Greek. It is formed by the word ἐγκέφαλος (enképhalos),to which αγ (an) is placed before, which in turn revoke the function of privative alpha. Thus so formed, the word anencephaly indicates a pathology which, generally speaking, refers to the brain’s absence.

he has no rights. The main objection is that these individuals are “used” to obtain benefits for others without they themselves gaining any benefit. Moreover the creation of a different status for them would lead to the extension of this status also for patient with other encephalitic malformations or terminal illnesses. To make an exception for that case would make it easier to make exceptions in other cases losing the fundamental values of our society.

The second opinion is to redefine the definition of death, substituting the concept of death as the complete and definitive cessation of all brain functions with the concept of death as the death of the only cerebral cortex. However this “new” definition contradicts the idea of death because of the presence of spontaneous breathing and of reflexes of cranial nerves. Anyway, death is a concept itself, separately from the transplant. The necessity of transplants has to boost research, not death.

CHAPTER 3 CONSIDERATIONS

The present Italian legislation is full of controversies and there are different opinions about it. It can be considered remarkable to a certain extent, but deplorable to another. As a significant result, it ends the paternalistic version, which provided that the last decision on the transplant was in the hand of the doctors or the parents of the donator. The explant will only be accepted after the deliberation of the donor, giving relevance to the will of the patient.

3.1 Tacit consent as an illiberal principle

Anyway, the principle of tacit consent could be considered illiberal, according to which, anyone who has not stated his or her dissent to transplantation, can be considered a donator. It could be considered illiberal because it gives to the institution an inalienable right of the individual, the right on his body. The State becomes an unauthorized interpret. The tacit consent is a manifestation of indifference towards the personal and religious liberty. The organ donation, which was a generosity act, becomes a bureaucratic one and the non-donation becomes morally deplorable, as a person who denies the explant of his organs after his death would deny the possibility to live to a sick person. Another observation is that the love toward others cannot be imposed, if it is not spontaneous, it is not love. Even one of the leaders of the A.I.D.O. (Italian Association of Donators), Umberto Caruso, has not a positive opinion about that law.

3.2 What do we owe to others?

As professor Sebastiano Maffettone highlights in one of his articles written on the newspaper “Il Sole 24 Ore”, on the 4th February 1999, the question we have to ask ourselves is “What do we owe to others?”[11] Without any doubt, we have negative duties, for example we cannot kill others, but we

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[11] Sebastiano Maffettone, Il Sole 24 Ore, 4th February 1999. Online article: http://centrotobagi.altervista.org/trapianti.html

have also positive duties, but these are not clearly defined, like a general assistance duty towards who is poor or sick. It is clear that we do not have to offend others but it is not clear if we have to help them to live. Should we donate a part of our body to help a sick person? Is it one of our duties? Or can the donation of blood be considered a duty? Or maybe we have a duty only when we personally know the person needing an organ? Can we encourage the disintegration of the "I"? It is evident that because of the vagueness of the moral duties, a law has rather to insist on the methods and procedures. This is what the new law does. The fact is that this law firstly affirms the individual will (instead of the doctors' and parents' will), but successively denies, in part, that individual will in order to favor transplants. Maybe, as Maffettone suggests, the tacit consent could be just a provisory expedient to solve the shortage of organs, just until a collective and individual conscience is formed.

3.3 An utopian law

The problem is that even analyzing the practical part of the law we can found some controversies. It is not really possible that the citizen could express his will and that this will could be made available to all the emergency rooms and the structures of organ transplant, nor it is credible that this administrative problem can be solved through the distribution to all citizens of an informatics health card. In fact it is difficult that in Italy, where the administrative office of the Asl are often unable to give basic health information, would be able to do what provided by this law. Moreover, several important aspects are not covered or mentioned by the law n.91. What about the foreign citizens who live in Italy? What about those citizens who will go to the hospital without documents and without having a written declaration on them? It is important to observe that this law makes us just an assembly of parts, in which we become a "public thing", such as an urban area.

CONCLUSION

We are not just objects, but human persons, and because of this difference, our body is important and it can be seen by the importance that every population has given and currently give to the defunct body. The things which associate all the population is the funereal rite, for example Egyptians gave importance to the preservation of the body with the mummification, instead Indians destroyed the body, but both the civilizations made ceremonies to make possible to the parents the veneration of the dead. The funereal rite is a fundamental step for the elaboration of the sorrow. So it can be considered an interest of the parents the necessity to celebrate the ritual. This right is reflected in art. 32, which guarantees the tutelage of the psychic well-being of the parents. From this point of view, the involvement of the parents in the donation decision can be legitimated. If the family decides to allow the donation, it becomes part of the ritual, even adding value to it. Otherwise, if the donation is done without the consent of the family, it can be considered a profanation of the funereal rite. Anyway it is true that the wellbeing of the parents is not more important than the tutelage of the interest of the dead individual to decide on his body. An equilibrium point can be the Spanish example, in which the help of the family is very important. The consent of the family can be an instrument to diffuse a collective conscience, in order to make the donation not only a solidarity act, but also even a fundamental part of the funereal ceremony. It is not easy to change habits, but succeed to include organ donation in our tradition could be a successful remedy to the organ scarcity.

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RIASSUNTO TESI IN ITALIANO

“TRAPIANTI UMANI: LA LEGISLAZIONE ITALIANA”

Come è possibile evincere dal titolo, questa tesi, di carattere legale, si propone di analizzare la legislazione italiana riguardo ai trapianti umani. E’ necessario innanzitutto comprendere cosa è un trapianto, quando e come è possibile procedere con tale operazione, e rendere noto il problema principale dei trapianti che si presenta a livello internazionale: l’insufficienza di organi disponibili. Viene così descritta la procedura del trapianto, ma ciò solo al fine di introdurre l’argomento e di rendere maggiormente comprensibile il principale obiettivo della tesi: la sintesi della situazione legale italiana in merito. Tenendo in considerazione fattori morali, principi bioetici ed usi e costumi italiani, che possono aver influenzato il progresso legislativo in merito, viene riportata una breve storia della legislazione italiana sui trapianti fino al 1° Aprile 1999, data di pubblicazione della legge n.91, ancora oggi legge di riferimento. Successivamente, non riportando letteralmente il testo, sono spiegati i contenuti principali di questa legge, il proposito, infatti, non è un’analisi analitica del testo, bensì un’analisi critica, che possa far emergere le principali incongruenze contenutevi all’interno. A seguito della consultazione degli archivi di diversi quotidiani, alla ricerca di scandali ed opinioni riguardo la pubblicazione della legge n.91, è stato possibile identificare le discrepanze principali. Ad esempio: la legge per essere tale necessita di un decreto che la renda attuabile, ma questo suddetto decreto non è mai stato scritto. L’attuale situazione italiana non rispecchia ciò che è previsto dalla nostra legislazione. Solo dopo aver reso chiara la situazione italiana, si è proceduto con una comparazione con altre legislazioni in vigore in altri paesi. Mostrate le varie scelte legislative che possono essere prese in merito a questo argomento, la tesi si conclude con delle considerazioni in merito al principio del “silenzio-assenso informato”, principio stabilito dalla legge n.91, secondo il quale siamo tutti donatori, a meno che non esprimiamo un diniego nel corso della nostra vita (principio per il quale, come detto, non è stato scritto un decreto attuativo). Questo principio è un principio liberale o può essere considerato una violazione della volontà del singolo individuo? Quale è il nostro dovere morale verso gli altri? Fino a quale punto dobbiamo essere disposti a sacrificare noi stessi per aiutare il prossimo? Il silenzio-assenso è un principio utopico o è facilmente attuabile? Non vi è certamente una risposta definitiva a questi quesiti, ciò che è certo è che non siamo oggetti, ma persone, ed in quanto tali, il nostro corpo è importante, anche dopo la morte, come viene dimostrato dall'importanza che ogni popolazione ha sempre dato, e dà, alla celebrazione del rito funebre. Forse proprio questo elemento, il rito funebre, può essere la soluzione al problema principale che comporta il trapianto d'organi: la scarsità di organi. Se la donazione fosse una fase del rito funebre, un valore aggiunto all'elaborazione del lutto e non più un semplice atto di solidarietà, solo allora il numero di donazioni potrebbe aumentare ed il numero di pazienti in lista d'attesa potrebbe finalmente diminuire.