

INFORMED OR PRESUMED CONSENT IN ORGAN DONATION: FRANCE AND ROMANIA LEGAL FRAMEWORK

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REZUMAT. Realizarea consimțământului cu privire la donarea sau primirea de organe este unul dintre cele mai dezbătute teme în materie. Când organele urmează să fie prelevate de la donatori decedați întrebările apar cu privire la felul consimțământului: informat sau prezumat? Când donatorii sunt vii consimțământul trebuie să fie explicit, în mod obligator, însă aici apar dileme etice relative la realizarea efectivă a acestuia: era donatorul pe deplin informat, era donatorul liber să aleagă, mai ales atunci când primitorul este un membru de familie sau cineva apropiat. Prin urmare a deschide dezbateră cu privire la consimțământ atunci când avem de a face cu donatori de organe, vii sau decedați este un demers complex, care ridică multe întrebări și dă puține soluții. Acest articol prezintă o analiză comparată a reglementărilor legale din Franța și din România privind tipurile de consimțământ la donarea de organe. Autorii arată care sunt asemănările și deosebirile dintre cele două reglementări, punând accent pe datele care vin din zona transplului de rinichi, considerat a fi organul pilot în materie de transplant și un miracol al secolului al XX-lea.

Cuvinte cheie: *Consimțământ Informat, Consimțământ prezumat, Donare de Organe, Transplant, Aspecte Legale.*

ABSTRACT. Giving the consent to donation or receiving organs is one of the most debated issues in the field. When organs have to be taken from deceased donors, the type of consent is the most debated: informed or presumed? When donors are alive, the consent must to be explicit, and mandatory, but there are some ethical dilemmas about its actual realization: if the donor was fully informed, if he/she was free to choose, especially when the recipient is a family member or someone close to the donor. Hence opening the debate on consent issues related to donors, living or deceased is a complex approach that raises many questions and gives few solutions. This paper presents a comparative analysis of the legal regulations in France and Romania regarding the types of consent to organ

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donation. The authors point out what are the similarities and differences between the two regulations, focusing on the data coming from the kidney transplants area, considered to be the pilot organ in transplantation and a miracle of the twentieth century.

Key words: *Informed Consent, Presumed Consent, Organ Donation, Transplantation, Legal Issues.*

1. General considerations on the Informed Consent

Informed Consent is an ethical concept that has become integral to contemporary medical practice. Informed Consent process implies two movements: one, to provide information in order to obtain a positive feedback; second, to have the consent and the permission from the patient to perform treatments, surgery or other medical procedures. The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) define in 2002, the Informed Consent as “a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation” (Guideline 4: Individual informed consent). This is the general rule, for adults and legally competent persons, who can understand the information, who can ask more information, who can accept or refuse treatments. But the pediatric practice is an exception from the general rule. From a legal point of view, minor patients are not competent to accept or to refuse treatments and physicians need to provide all medical information to the legal representatives, who are, in the most of the cases, the parents of the patients.

Providing information and obtaining informed consent in pediatric practice is a complex scenario for all those involved: clinicians, parents, children, legal representatives, ethical counselors, psychologists. Parents have legal and moral authority to make decisions on behalf of their children, although that authority is not absolute and their decisions must be in the best interest of the child (1).

Organ donation and transplantation is considered one of the greatest therapeutic advances of the last century. The first kidney transplant was performed in 1952 in Paris and in 1954 in the United States of America. In order to realize the transplantation, the kidney can be taken from deceased donors and also from the living donors (33). The kidney is the most transplanted organ in the

world. Whether in France or Romania, kidney transplant programs increased significantly. But despite all efforts, as everywhere in the world, there is a serious lack of organs for transplants. Many patients with kidney insufficiency are waiting for an organ to be available, according to statistics and data published in France (by the Agency of Biomedicine) and in Romania (according to Agenția Națională de Transplant) (3, 4).

Ethical issues of kidney transplantation are part of the central topics debated in Europe because many people are suffering from kidney failure and the waiting list grows every year. Those who are in charge with state programs are aware that kidney transplantation is the most economical solution, more affordable than repeated dialysis which does not ensure a good quality of life compared to the transplantation (3).

2. Material and methods

As material we have taken into consideration the legal regulations, in force, in Romania and in France, in 2017. We therefore took information from the official website of the two National Agencies of Transplants, in order to make comparisons between the two legal frameworks. Our approach is a mixed, qualitative and quantitative research. The used methods are the descriptive study on the data published by the two official institutions and on the two types of legislation under consideration. The study aims to analyze the French and Romanian regulations on the consent of donor, using different comparative tables. Each table will have a specific topic and will include a certain number of statements; if a statement respects the text of the law then it will be answered by „yes”, the reverse will be „no”. Some statements, that need clarifications, will be noted differently.

Example:

Table 1.

States	Legislation Romania	Legislation France
XXX	Yes	No

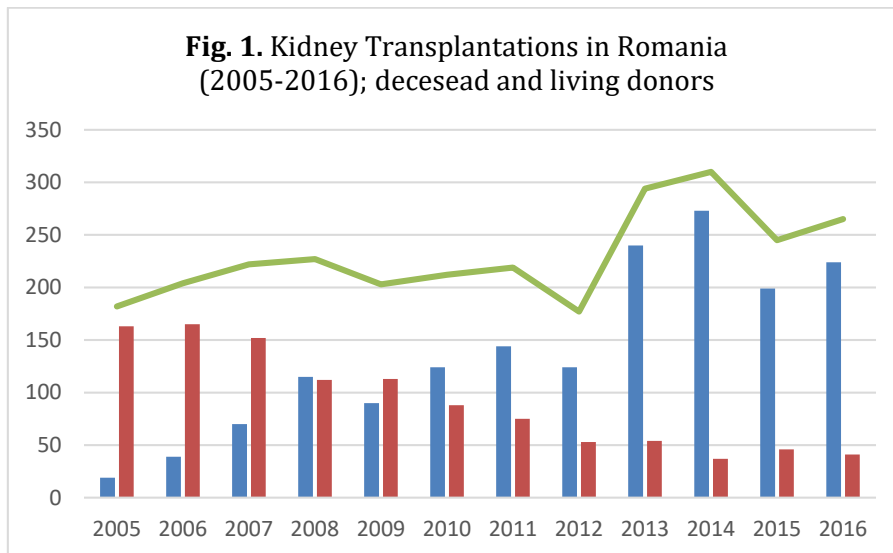
The subjects developed in our study are the following:

- State of the art on kidney transplantations in France and Romania;
- General information on the French and Romanian laws on organ donation;

- Kidney removal from living persons;
- Kidney removal from deceased persons;
- Consent;
- Sanctions in case of trafficking organs.

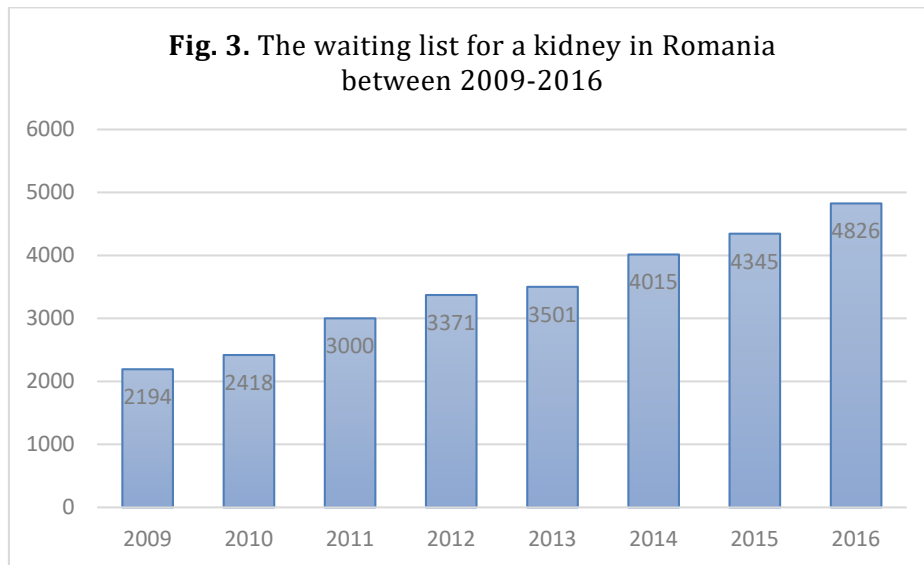
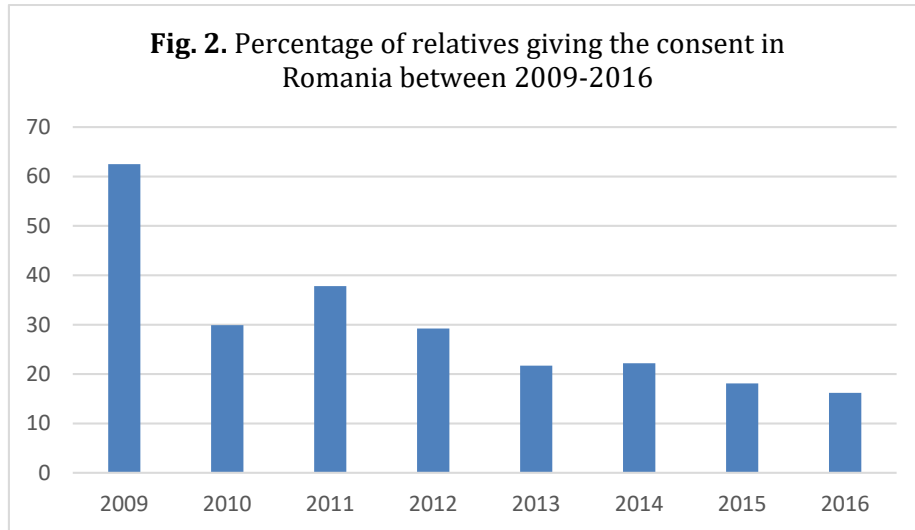
State of art on kidney transplantations in Romania

The National Agency for Organ Transplantation in Romania (www.transplant.ro), regularly publishes data on kidney transplants carried out each year. In the following figures we have summarized the grafts carried out between 2005 and 2016.

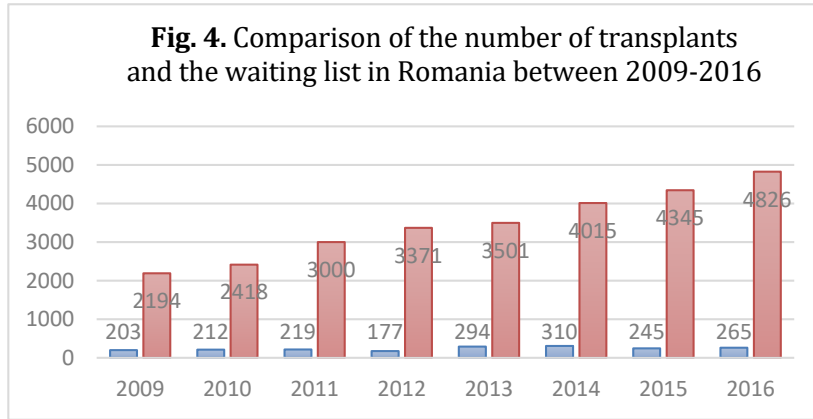


- Kidney transplants from brain death donors
- Kidney transplants from living donors
- Total number of kidney transplants

Between 2005 and 2016, in Romania, there was a tendency of kidney transplants augmentation. There was a decrease in transplants taken from living donors and an increase from deceased donors, but the trend was reversed in 2008, when the proportion of kidney from deceased donors was higher than before.



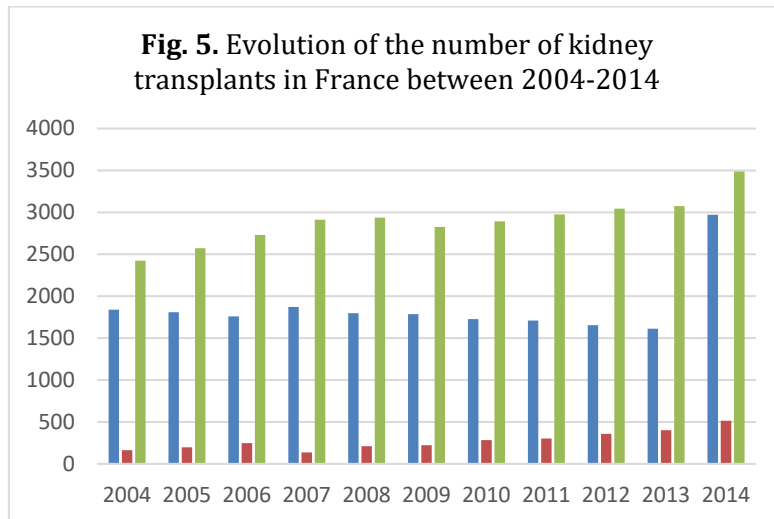
The waiting list has more than doubled between 2009 and 2016, now reaching nearly 5.000 patients waiting for a kidney, accentuating the problem of the lack of organ, despite a downward trend in family refusals.



■ Number of kidney transplants ■ Patients in the waitlist

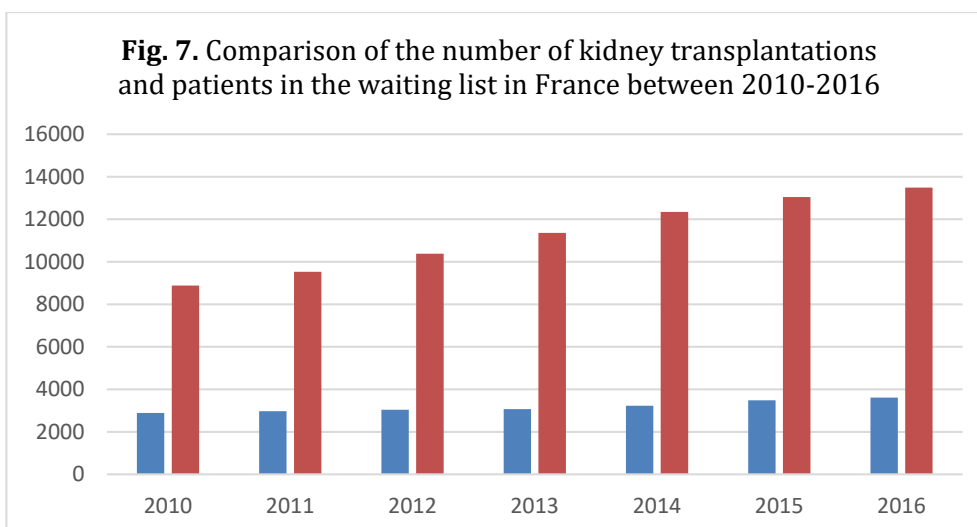
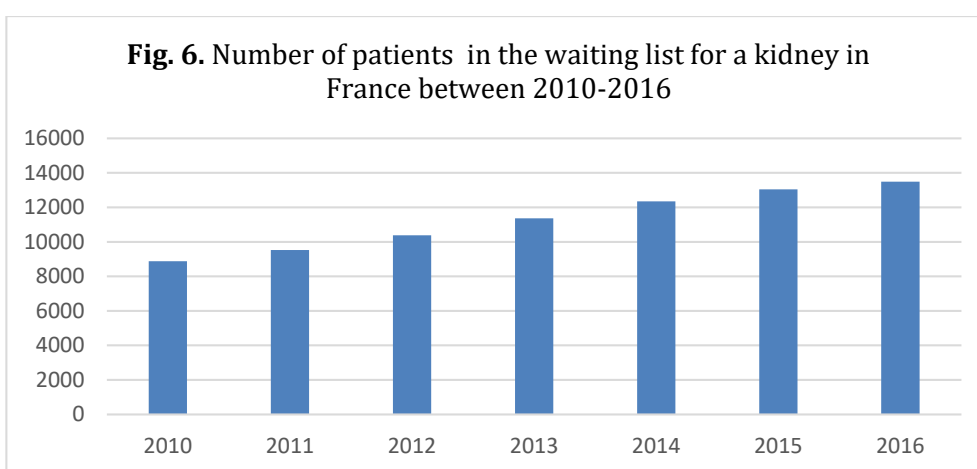
State of the art on kidney transplantations in France

These data are available on the official website starting from 2010.

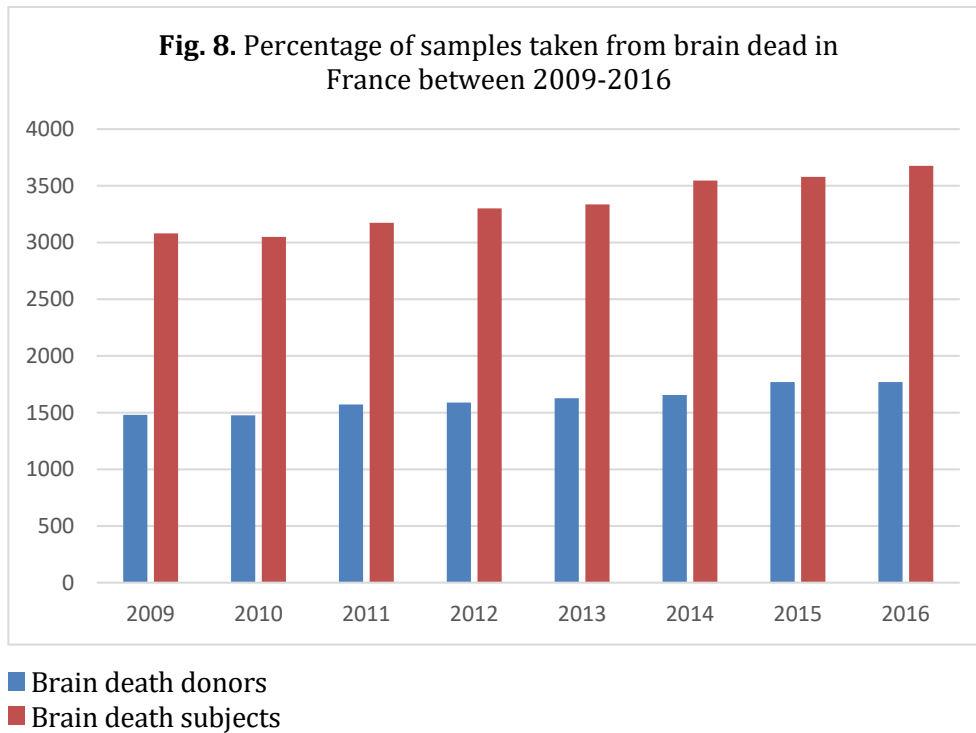


■ Number of brain death kidney donors
 ■ Number of living kidney donors
 ■ Total number of kidney transplants

Between 2004 and 2014, in France, kidney transplants have remarkably increased due to a constant evolution each year, from about 2.500 in 2004 to 3.500 in 2014, which is a significant step forward. Unfortunately, the results are rather altered by the increase increase in the number of patients on the waiting list, which almost doubled between 2008 and 2014, the last estimates exceeding 10.000. The rate of refusal of kidney removal remains approximately constant and ranges fairly regularly around 40%.



■ Number of kidney transplants
 ■ Number of patients in a kidney waitlist



From the figures above (1 to 8), the first observation is that between France and Romania, in spite of the figures having a ratio that is ten times higher in France, there are some similarities in the overall situation: transplants have increased, but the waiting list too. The refusal rate remains comparable which does not help in solving the problem of lack of organs (3, 4).

The Consent of the donor

The “presumed consent” means explicitly refusing to “leave” the group of potential donors or “opting out”.

Explicit consent means asking to be a donor to “enter” the group of potential donors or “opting in”.

The families or the relatives of the patient in the brain dead conditions may testify to the agreement of the deceased. Indeed, each modality of consent can be qualified according to the power granted to the donor's family to revoke its decision to donate or refuse.

For example, two other sub-categories of presumed and informed consent can be defined in terms of the decision-making power of families: explicit consent strong: not an organ donor unless explicit expression of willingness to give and families / relatives have no decision-making power; explicit consent **low**: the family has the final decision-making power, they can accept the giving even if the deceased person has not registered as a donor or has not explicitly stated his/her willingness to give. They may also refuse to donate an organ, even if the person has registered as a donor.

Fort: The family cannot refuse the gift or even revoke the will of the deceased even if the person has not spoken during his lifetime (France - since January 2017)

Presumed Consent low: No withdrawal made if the family refuses even if the deceased has a donor card.

The place of the family in the decision is important for obvious reasons of ethics and morality.

3. RESULTS

The laws regulating organ transplantation in Romania and France

Romania has as a general framework in this matter - Law no. 95/2006 regarding Health Reform, in force from 2011, articles 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159.

In France, the laws and regulations applicable to organ donations are the Civil Code, Article 16 of Chapter 2 and the Code of Public Health, Article L1211-1 of the Single Chapter.

TABLE 1: GENERAL INFORMATION ON FRENCH AND ROMANIAN LAWS CONCERNING ORGAN DONATION - France: Code of Public Health

(Code de la Santé publique) Article L.1211-2; Romania: Law no. 95/14 April 2006 Article 144

Topics	French regulations	Romanian regulation
Consent	Presumed	Explicit
Gratuity	Yes	Yes
Anonymity	Yes	Yes
Therapeutic Purpose	Yes	Yes
Prohibition of Advertising	Yes	Yes

TABLE 2: SAMPLES FROM LIVING DONORS - France: Code of Public Health
(Code de la Santé publique) Article L.1231-1; Romania:
Law no. 95/14 April 2006 Article 144

Samples from living donors	French regulations	Romanian regulation
A donor able to decide for him/herself	Yes	Yes
A minor with the consent of the legal representative	Yes	Yes
Prohibition to take an organ, tissue, cells from a person who does not have the capacity to decide	Yes	Yes
Prohibition to take an organ, tissue, cells under any constraints: family, professional, financial, moral.	Yes	Yes
Prohibition to make the donation mandatory by a fact or legal act	Yes	Yes
Decision validated by an expert committee	Yes	Yes
Possibility of cross-donations in the case of incompatibility between donors and receivers	Yes	Not mentioned in the Romanian law - No

TABLE 3: SAMPLES FROM BRAIN DEATH DONORS - France: Code of Public Health
(Code de la Santé publique) Article L.1232-1; Romania:
Law no. 95/14 April 2006 Article 147

Samples from brain death donors	French regulations	Romanian regulation
Disclose the identity of the deceased donor is forbidden	Yes	Yes
The assessment of the death prior to the sampling	Yes	Yes
Independence of the physician who declares the death statement	Yes	Yes

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<p>Sampling of organs is done only after getting the written consent of a family member or relative</p> <p>*If the deceased person had already expressed the consent during his lifetime by notarial act in the National Register of Organ Donors (Article 145-5 of the law no. 95/2006)</p>	Yes	No*
<p>Organ removal is excluded if there is a risk of contamination by an infectious disease</p> <p>*In France there is an exception in the law according to which if the benefit is superior to the risk a quick decision is requiring in urgent situations.</p>	No	Yes*

TABLE 4: CONSENT - France: Code of Public Health (Code de la Santé publique) Article L.1211-2; Romania: Law no. 95/14 April 2006 Article 144

Consent	French regulations	Romanian regulation
Written, free, informed	No	Yes
In the absence of a written will of the deceased donor, it is presumed.	Yes	No
If the donor does not have the opportunity to express it, then it may be given in writing by a family member or legal representative.	Yes	Yes
If the donor is minor or incompetent it is given by a parent or a legal representative	Yes	Yes
The sampling is possible even if the consent cannot be obtained, after several attempts to contact the family or a relative.	Yes	Yes

TABLE 5: SANCTIONS - France: Criminal Code, Section 1 and 2, Article L.511-1;
Romania: Law no. 95/14 April 2006 Articles 154, 155, 156, 157, 158 and 159.

Sanctions	French regulations	Romanian regulation
Organ, tissues, and cells harvesting, without having the consent	5-7 years in prison	7 years in prison + 100,000 euros fine
Removal of organs, tissues, cells, that compromises forensic autopsy	1-3 years in prison	2 years in prison + 30,000 euros fine
Advertising in favor of a person for the purpose of obtaining one or more organs, tissues or cells for material advantages	2-7 years in prison	7 years in prison + 100,000 euros fine
Organ trafficking including the introduction or removal of tissues and cells without authorization	3-10 years in prison	5 years prison + 75,000 euros fine

4. DISCUSSIONS

Generally speaking, legal regulations in France and Romania are quite similar, especially concerning conditions of donation: free and anonymous, the therapeutic purpose of donation, and the prohibition of advertising

Regarding the consent, a certain difference is highlighted; France adopted and implemented the presumed consent to organ donation. This is a strong point that differentiates it from Romania, which remains on a conventional pattern of explicit consent. However, it remains free, informed and written.

But in practice, and especially with regard to post-mortem organ donation in the many cases where the deceased person did not make known the desire in favor during his/her lifetime, the impossible question arises on what is the opinion of a deceased person on organ donation.

Also, the donor card has no legal value in France and Romania. It is up to relatives to make a decision, which is difficult most of the time and, as a consequence, inevitably, a high number of refusals appear despite the difficulty related to the shortage of organs.

Regarding the living donors levy, common points have been noticed, especially on the fact that the adults must all be capable, with the agreement of the legal representative for the minors and the decision of a committee of experts. The difference lies in the possibility of cross-donations in case of incompatibility between donor and receiver of the same family - it is possible in France but in Romania this possibility was not mentioned.

Regarding the sampling of deceased persons, there are also many similarities, especially concerning the disclosure of the identity of the donor, the report of death in advance, the independence of the physician who made the death statement and the team in charge of sampling.

The main differences lie in the existence in Romania of an exception in the law to the written consent rule. Indeed, this consent does not have to be taken from relatives if the deceased person had already expressed his/her wish to donate organs by notarial act registered in the national register of organ, tissue and cell donations. In France, this is impossible because as presumed donors, French people do not have to express the 'yes' because it already is, legally. In France one may only express the 'no' from a legal point of view. So, in France there is a register of 'no' to donate organs.

Another important difference is that in France it is possible to transplant an organ that has been the subject of an infectious disease if the doctor responsible for the transplant considers that the benefit / risk ratio is in favor of the transplant. This is not the case in Romania from a legal point of view.

French and Romanian laws are very similar but some differences are notable, fact that clearly shows a strong legal link between the two countries.

On the other hand, we can discuss about the allocation and distribution of organs at a national level in both countries. In France, the management of the national waitlist is under the responsibility of the National Agency of Biomedicine. The distribution rules are drafted by a national expert group, in order to reduce the inequalities of the access to organs between patients and to optimize the efficiency of the distribution of organs. There is still quite a large variation between regions and teams, as shown by the shortage of organs. These rules are available on the website of the Biomedicine Agency in France.

If the subject's age is less than 18 years old then the organs should be allocated primarily to pediatric recipients, regardless of adult priorities (no adult local kidney). Only the absence of compatible pediatric blood group recipient allows the organ to go to an adult. If the age of the subject is above 18 years it is considered to be local. The organ does not go to patients of national or inter-regional waitlist.

In Romania, there are no rules of this kind for the assignment of transplants even if it remains in the field of the National Agency of Transplant.

Organs taken from deceased people are an invaluable and rare resource. The distribution and allocation of organs is the essential link between harvesting and transplants. The distribution and attribution rules for organs must respect the principles of equity, medical ethics and they should aim to improve the quality of care.

These rules refer to notions of priority and territorial dimension. These concepts reflect the desire to find the balance between a distribution as equitable as possible and the technical constraints inherent in the harvesting, transport and maintenance of organs quality.

The purpose of these rules is to take into account the urgency of the transplant or the particular difficulty of accessing it for certain patients, while seeking optimal use of the organs. The evaluation of the consequences of these rules on the waiting time of patients and the results of transplants will allow their improvement as technical progress.

The Informed and presumed Consent are the major differences between France and Romania, even if, globally speaking; the two policies are very similar. Regarding the allocation of organs in France, rules have been published and although it is not very effective, particularly because of the shortage of organs, France has a certain advantage over Romania but they still cannot solve all problems and find solutions for all patients.

CONCLUSIONS

The first conclusion of the paper is that between the legal regulations in Romania and France concerning kidney transplant there are some similarities and significant differences. As a similarity, the two countries have adopted specific laws in this area; they have national institutions that manage policies in transplantation. France and Romania share the principles of anonymity, free of charge, therapeutic purpose and the prohibition of advertising.

A notable difference is the modality of achieving the donor's consent, as an essential condition in the situation of a deceased donor. France is one of the countries that have decided to adopt the easier variant, that is to say, the presumed consent. In exchange, Romania chose the explicit consent procedures.

Other differences concern the ways in which organs are allocated. In Romania the rules are not clearly established and give the green light to arbitrary decisions, whereas in France specific rules have been published, in order to try to respect the principle of equity and to avoid confusions and criticism.

The provided sanctions are generally more severe in France than in Romania. In addition to a prison sentence heavy financial penalties are applied in France, with a minimum of 30.000 euros up to 100.000 euros fine.

All this information and data will have to be verified by subsequent research, carried out in different profile centers located in France and Romania. The existence of a considerable number of these types of institutions is a growing need in view of the situation of patients waiting for a kidney transplant that can save lives.

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