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Organ transplantation law in Chile: historical evolution, clinical, social and bioethical implications

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***Abstract*:**

Introduction and Purpose: *Organ donation and transplantation have undergone a series of legislative changes over time. The aim of this bibliographic review is to analyze the historical evolution of the law and the repercussions it has had on ethical, social and clinical aspects.*

Material and Method: *A descriptive review was carried out using platforms such as Google Scholar and Scielo, obtaining several articles which were analyzed according to criteria in accordance with the fulfillment of the objectives.*

Results: *Throughout history, the development of medicine in the field of transplantation in our country has made it necessary to legislate in order to regulate and meet the needs that arise as a result of these advances. Thus, from a basic Law (19.451), a series of modifications were made, currently counting with the concept of 'Universal Donor', in a constant attempt to increase the number of donors. This law has brought bioethical repercussions in terms of concepts of life and death, current change to presumed consent and reciprocity as main issues. Important points in favor of donation are information, solidarity, convenience and trustworthy physician. The points against donation are fear of death and mutilation, lack of information and anticipated disconnection. In clinical practice the donor rate has remained low and as of 2015 approximately 4 million people qualify as non-donors.*

Conclusions: *Over time a series of measures have been implemented seeking to increase the number of donors, given the growing demand for transplants, however, we can conclude that these measures have not been effective due to the lack of knowledge of the population and the maintenance of clinical practices of yesteryear.*

Keywords—Organ transplantation; bioethics; bioethical issues; Chile.

I. INTRODUCTION

Organ donation is a voluntary, altruistic and free act, by which a person or their family (as a representative) decide to donate organs, so they can be removed from the body and implanted in another person. Organ donation can be carried out by living people who donate an organ to a compatible donor (as long as this does not alter the vital functioning of their body) or by deceased patients, in which they request an organ to be donated to another person [1,2].

Organ donation can be carried out by living people who donate an organ to a compatible donor (as long as this does not alter the vital functioning of their body) or by deceased patients, in which family authorization is requested. In the case of deceased donors, the removal of the donated organs and tissues is performed in the surgical unit, by highly specialized surgeons, who carefully procure them, safeguarding the person's body, which will then be handed over to their relatives. [3]

Transplantation is a medical treatment performed when there is an irreversible organ failure, and all other treatment alternatives to recover the organ have already been evaluated. It involves the removal of the failing organ and its replacement with a healthy one from a donor. The organs most frequently transplanted in our country are: heart, lung, liver, pancreas and kidneys. [4]

From a legal point of view, organ, tissue and material transplants have a close relationship with the individual rights that are inherent to the human person, with legal, philosophical, scientific, sociological and anthropological implications. This relates fundamentally to the ethical-legal aspect, where it is shown that organ donation constitutes difficult moral, philosophical, religious, sociological and anthropological decisions and discussions that give rise to acute controversies in the context of contemporary debate and discussion.

In our country, the laws that regulate the processes of donation and transplantation are the following:

- Law N°19.451 which establishes the norm on transplants and organ donation.

- Law N° 20.413 - N° 20.673 which modifies Law N° 19.451 in order to determine who can be considered organ donors.

According to this law, any person over 18 years of age is automatically considered an organ donor once deceased, except in the case of a reliable statement made during life that establishes the deceased's will to not be a donor, and the exception also includes contraindications for possible disease transmission, such as being a HIV positive person, presence of a serious uncontrolled infection or metastatic cancer.

On the other hand, the law also establishes the concept of founded doubt, which means that the potential donor's condition must be defined on the basis of a system of consultation with legal representatives. In any case, in clinical practice, if there is opposition on the part of the deceased's legal representatives, even if the deceased has expressed before his or her wish to be a donor, the decision of the representatives is respected. In addition, there is also the possibility of being a living donor when the person turns 18 years of age and expresses the will to donate, as long as a series of medical requirements are met, which include a rigorous evaluation. [5,6]

In order to understand the current state of the law in our country, it is vitally important to understand the historical context of organ donation and transplantation, both nationally and internationally, which will allow us to establish causal relationships based on the chronology of the most relevant events.

When analyzing the repercussions of the transplant law in Chile, it is absolutely necessary to do so from different perspectives, which allows us to understand its implementation, and also provides tools to adopt a critical position with respect to the positive aspects that the law includes, as well as the different legal voids that it may bring with it.

A combined analysis of the clinical, social and bioethical repercussions of the historical evolution of the transplant law in Chile will allow a more global understanding of the current situation in our country and the different situations that arise in clinical practice, the different debates that are currently taking place on the subject, and to elucidate the possible future of donation and transplants in our country.

II. OBJECTIVES

A. *General*

Analyse the historical evolution of the transplant law in Chile and to establish the clinical, social and bioethical repercussions involved.

B. *Specifics:*

- Review the historical evolution of the transplant law in Chile.

- Describe the current state of the transplant law in Chile.

- Analyse the clinical repercussions of the transplant law in Chile.

- Recognise the social consequences of the transplant law in Chile.

- Determine the bioethical implications of the transplant law in Chile.

III. METHODOLOGY

A. *Design*

A descriptive review was conducted based on legal documents and historical articles.

B. *Search strategy:*

- Firstly, a search was carried out in Google Scholar, the Chilean National Congress and the Chilean Ministry of Health for legal and historical documents published by different bodies, also various studies and scientific articles belonging to various societies and authors who analyze the subject in question from different aspects were searched. This search only included documents published in Spanish. Subsequently, a search was carried out for bibliographic reviews and articles from the literature of the Scielo Scientific Library, with no date limit and considering only documents in Spanish. For the search of original documents, we searched the following equations: "Donación de órganos en Chile", "Historia de trasplantes en Chile", "Ley de trasplantes en Chile" and "Ley de donación en Chile". The bibliographic references of the articles and publications were also analyzed in order to rescue other studies and information that could potentially be included in the review.

C. *Inclusion and exclusion criteria*

After the initial search, 38 documents were located, from which we excluded those that were not relevant to the aim of this review. Finally, 24 files were selected, including 9 legal documents, 3 journal articles, 3 surveys, 2 literature reviews, 5 circulars from health agencies, 1 degree thesis, 1 news magazine item.

In order to proceed with the selection, abstracts were reviewed and in necessary cases the complete documents in order to decide if the information exposed was related or not to our objective.

D. *Data analysis*

The information analyzed was first organized into different groups according to whether it responded to each objective, general or specific.

In order to carry out the historical analysis of the donation law in Chile, the information was organized in chronological order, which allows for continuity in the established relationships and justifies the occurrence of events and the consequences of each historical event.

The analysis of the repercussions of the law in different areas was carried out on the basis of the positions of the various authors and entities that carried out the bibliographical sources used, in addition to a personal analysis with a global perspective based on all the documents reviewed.

IV. RESULTS

A. *Historical legal analysis*

The history of organ transplantation begins many years ago, with evidence of non-visceral tissue transplantation even existing since prehistoric times. However, the modern era of transplantation began between 1900 and 1959, with experimentation on animal models, the improvement of surgical techniques such as vascular anastomosis, and the study of clinical manifestations and graft rejection.

Like many things in medicine, it was during the First and Second World Wars that transplantation and grafting were developed as a therapeutic alternative to the increasing number of gunshot wounds and burns. [1]

During this period, the immunological phenomena of sensitization, memory and tolerance were studied and it was proposed that for a transplant to be successful, it was necessary for the donor and receptor to be monozygotic twins. The kidney was the experimental model by excellence, given its parity and the anatomical advantages of its vascular pedicle for anastomosis. However, it is at this point that the ethical dilemmas begin, questioning the fact of extracting an organ from a living, healthy person to save the life of another, knowing that it could have consequences for the donor. [2]

As science advances and new immunosuppressive drugs are developed, experimentation is transformed into clinical use, opening the door to transplants between unrelated subjects, which allowed the massification of transplants and the increase of ethical dilemmas. [1]

The first kidney transplant in the world was performed in December 1954 in the USA involving identical twins, with successful results. In the face of this scientific development, our country has not lagged behind. Thus, in Chile, the first kidney transplant with cadaveric donor was performed on November 22, 1966, while the first kidney transplant with living donor was performed on January 4, 1968, both at the Clinical Hospital of the University of Chile. That same year, the first heart transplant was performed in Chile at the Hospital Naval de Valparaíso, barely a year after the first heart transplant of its kind in the world. [3]

In this context, Law 18.173 was created on 15 November 1982, which incorporated Book IX of the Health Code about the use of organs, tissues or parts of the body of a living donor and the use of cadavers or part of them for scientific or therapeutic purposes, being one of the first attempts to legislate on transplants. This law, in basic terms, establishes that any person may dispose of their remains for scientific, educational and/or therapeutic purposes, expressing their will in writing and revoking it in the same way. It also establishes that persons who have died in public or private hospitals, or who are in establishments of the Forensic Medical Service and who have not been claimed by their relatives within the time established by regulation, will be destined for the purposes already specified. Likewise, in the event that the relatives do not express their opposition to the remains of the person being used for these purposes, or that they give their authorization to the director of the establishment. In the case of living donors, it establishes that tissues or organs may be removed for grafting to another person only for therapeutic purposes and free of charge. [4]

However, these legal provisions meant the registration of a small group of people as voluntary donors in case of death, and in those cases in which the deceased did not express his or her will during life, the law requires the authorization of the family for organ procurement, being this response negative in the majority of cases.

By 1990, cornea and kidney transplants were already established and successful procedures in our country. Slowly, liver transplants were taking place in the treatment of cirrhosis or other liver lesions, which increased the demand for organs and also highlighted the lack of donors, especially cadaveric donors. Non-profit organizations such as the Corporación Nacional de Fomento de Trasplantes were created in response to the lack of organs for transplantation, founded mainly by physicians involved in transplantation. Given these facts, the need for a new law to regulate the issue of transplants and organ donations became imperative.

This is how Law 19.451 was born, which was proposed as a project of law on September 13, 1990, based mainly on the respect for the freedom and dignity of the donor, and the right to health of the receptor. After years of analysis and modifications, it was finally promulgated on 29 March 1996 and published on 10 April of the same year. Although this law has undergone subsequent modifications, it establishes the basis for the regulation of organ transplantation and donation.

In general terms, it establishes that organ transplants may only be performed for therapeutic purposes and in authorized establishments, with donation only being free of payment. Regarding the removal of organs from living donors, it establishes that it may be performed on persons whose physical conditions are certified by at least two different physicians from those who are going to perform the removal or transplantation. Likewise, the donor, previously informed of the risks of the removal, must express his or her consent in a document signed before the director of the establishment, which may be revoked at any time before the removal, without the need for any formality and without any liability of any kind for the donor.

Regarding the removal of organs from deceased donors, it is necessary to define the concept of death in a unanimous and unequivocal manner, a diagnosis that will be granted when there is a total and irreversible abolition of all encephalic functions, accredited by clinical parameters and qualified tests or examinations. The medical team that grants this certification must not be related to the team that performs the transplant and at least one of them must be a neurologist or neurosurgeon.

Once this concept of death has been defined, any fully capable person will be able to dispose of his or her body or parts of it for the purpose of therapeutic transplantation. In order to do so, the donor must express his or her will before a notary. Likewise, at the time of obtaining or renewing an identity card or driver's license, all persons will be asked by qualified personnel whether or not to donate their organs for transplantation purposes after their death, making them aware that this is a voluntary decision and therefore they are free to answer as they wish. Those who say yes will receive a donor card to certify their status as a donor. In addition, people will be able to express their will when they are admitted to hospital.

With regard to the removal of organs from deceased persons who have not expressed their authorization during their lifetime, who are minors or legally incapable, it may be carried out provided that the authorization of the spouse or legal representative, as the case may be, is obtained. In the absence of both, the closest blood relatives in the straight line and, lastly, in the collateral line, shall be consulted. Such authorization must comply with the formalities established by law.

In contrast to Law 18.173, Law 19.451 establishes legal sanctions with prison sentences for any action performed for profit. It also establishes regulations regarding the import and export of organs; the creation of a registry of potential organ receptors, determining their priority for the reception of organs when they come from cadaveric donors, in charge of the Institute of Public Health; the creation of an advisory commission of the Ministry of Health called 'National Corporation of Organ Transplantation', with the objective of studying and proposing plans, programs and norms regarding the subject; and finally it includes modifications to the Sanitary Code in book IX, such as the repeal of article 149. [5]

Over the years, and in spite of the access and economic difficulties that organ transplants pose, mainly for patients in the public sector, they have become an increasingly available therapeutic alternative for the population. In 2006, 229 kidney transplants, 74 liver transplants, 18 heart transplants and 5 lung transplants were performed in Chile, according to data from the Transplant Corporation.

However, despite the measures implemented in Law 19.451, which sought to regularize the issue of transplants and encourage organ donation, the number of donors remained below the Latin American average, reaching values of 9 donors per million inhabitants, compared to Uruguay and Argentina with 17 and 15 donors per million, respectively, and far below European countries such as Spain, which has the best rates worldwide with 38 donors per million.

This led to a renewed need for legislation on the issue, due to the poor effect of the mechanisms implemented to encourage donation, either due to their insufficiency or the population's lack of knowledge.

Under this new national reality, a new legislative project was presented on 18 April 2007, proposing strategies such as extending the procedures where a system of obligatory consultation on the intention to donate organs or not will be applied, and studying a way to contemplate minors as potential donors in case of death. Most importantly, the concept of "Automatic Donation" should be included, i.e. to consider people who do not express their opinion as donors under the law, who may, whenever they deem it necessary or pertinent, express their will not to donate in writing in any instance where they are consulted. This modality seeks to imitate an important part of the systems applied in Europe, particularly Spain, adapting to the Chilean reality and amplifying the donation spectrum of the time. [6]

Thus, in January 2010, Law 20.413 was passed, which amends the previously existing Law 19.451, incorporating the concept of "Universal Donor", stating that ".... Any person over 18 years of age shall be considered, by the sole authority of the law, a donor of his or her organs once deceased, unless in life he or she has expressed his or her wish not to be a donor in any of the established ways...". It also safeguards the identity and privacy of the deceased donor and the receptor in accordance with the law on the protection of privacy. It establishes that transplants from living donors can only be performed between related persons, as long as it does not seriously harm the health of the donor and there are prospects of success in improving the health of the receptor, and the consent of the donor can be revoked up to the moment of the surgical intervention. It orders the Ministry of Health to create a national transplant coordinator, through the Subsecretaría de Redes Asistenciales, and the creation of a national registry of non-donors, public and readily available especially for health establishments. [7] [8]

Prior to Law 20.413, the Transplant Corporation coordinated at the national level the medical teams in charge of organ extraction and procurement for transplantation, but after its enactment, all efforts were focused on the new governmental entity Coordinadora Nacional de Trasplantes (National Transplant Coordinator). [9]

With the change in the approach to donation, from a system of required response to one of presumed consent where everyone is a donor until they state otherwise, it was hoped to increase the donor rate, however, one year after the enactment of Law 20. 413 the rate fell to its lowest number in 15 years, which again led a group of deputies to propose a legislative project on 9 August 2011, under the idea that the general lack of knowledge about the law does not allow the population to make a decision at the time of being consulted and that due to the long period in which the documents are renewed, it conditions those who clarify their doubts to go to the Civil Registry and/or Municipality where the documents were obtained to declare their option to be donors, returning in practice to the model of Law 18.173. [10]

On 29 May 2013, law 20.673 was passed, establishing that any person over 18 years of age is a donor once deceased unless, even before organ extraction, reliable documentation is presented before a notary, in which it is stated that the person in life expressed his or her will not to donate. Also, in the event that several people are in an equal position to receive an organ, this law included as a criterion for prioritisation the fact of whether or not they belong to the Non-Donor Registry. In this way, those who are registered have a lower priority than those who are not. [11]

Despite the progress made in terms of legislation, the availability of organs is insufficient to meet the existing demand. By 2015, epidemiological changes and advances in medicine have led to an increase in the number of patients who are candidates for transplants, who see in this therapeutic measure an improvement in their quality of life, an increase in survival and even the recovery of the autonomy necessary to reintegrate into society.

This is why a new legislative project proposes the possibility of "organ cross-donation". In our country, organ transplants between related living persons are possible, however, it may happen that the related donor is not compatible with the receptor. One solution to this is the exchange of donors between donor-recipient couples unknown to each other, who are in the same situation, so that both receptors receive a compatible kidney and the donors perform their wish to donate. This method, tested in other countries, has had excellent results in terms of graft survival and recovery of the receptor, as well as donor satisfaction. It is known that a graft from a living donor has a longer short- and long-term survival, so this measure seeks to increase the supply of living donors to improve outcomes and meet the needs of the growing waiting list. [12]

Thus, on 3 February 2017, law 20.988 was enacted, the latest modification to date of law 19.451, which approves and regulates this new modality, creating a national registry of donor-recipient couples, under the responsibility of the Institute of Public Health, with the aim of facilitating the search for biologically compatible couples and applying prioritization criteria for transplantation. [13]

B. Bioethical, social and clinical implications of organ transplantation

1) Bioethical implications:

Organ donation involves many protagonists: society, the state, the medical establishment, the judiciary, etc., as well as being a subject that leads to reflection in many fields of thought, including bioethics, because organ donation involves concepts that have always intrigued mankind: life and death. [1].

As an example, during the First World War: Since the kidney is a paired organ, it was the first organ to be experimented as a transplant. The ethical question arose: Is it lawful to remove organs from a living, healthy subject in order to transplant it into another and thus save his or her life? Then the transplantation procedure began to become more widespread and other organs began to be used. This raised a new ethical controversy: Human beings were being used as guinea pigs, not unlike what was performed in Nazi concentration camps. This led to the emergence of Research Ethics Committees.

The increase in transplantation led to a shortage of donations, so the remaining option was the cadaver donor. And here again another milestone in bioethics arises: the definition of death and the concept of brain death. The former has no further dilemmas, being defined as "cessation or termination of life". However, it is the criteria used to say that it has occurred that causes controversy. In Chile, the term encephalic death is used as a synonym for real, definitive, unequivocal and unequivocal death of the human being. This has repercussions since some consider encephalic death as a point of no return towards death, but not death itself.

With the new amendments to the donation law on presumed consent, some authors are of the opinion that the act of donation should arise from the will of the person expressed during the course of his or her life and not as presumed consent. Others are of the opinion that it is a measure that seeks the greatest possible benefit for society. It is an altruistic view of the problem: "the greatest good for the greatest number of people". New questions arise, such as: what about informed consent and the principle of autonomy? Clearly it is possible to refuse to be a donor by registering as a non-donor, yet people are not properly informed. Is the rule of presumed consent a confiscation mechanism? There are many views on this issue, but the presumed consent system is not entirely confiscatory in nature, insofar as the living donor and his or her relatives can always object to the initial destination set by law by the State, so it is still framed in terms of altruism. [14]

Another set of ethical problems related to organ transplants concerns their allocation to one patient among many who could benefit from this treatment. This is an ethics of distribution. It is an issue of justice that has been resolved by ensuring independence between a medical team treating the donor, those treating the potential receptor, and those allocating the organs. It seeks to avoid biases or forms of pressure and to base organ allocation by establishing priorities that include histocompatibility, probability of success, associated pathologies, time on the waiting list, age and in the case of some organs, severity of the patient. The current law states: "If several persons are in equal conditions for the reception of an organ, the fact that they are not registered in the Non-Donor Registry must be taken in consideration in order to prioritize them with respect to those who are". This can be interpreted in several ways: as a form of unfair pressure for those who do not consider organ donation as an option, or as a fair measure for those who are donors. Can a person really be forced to be a donor? Does not doing so make the person less deserving of this benefit? It is valid to argue that if one is willing to receive an organ, one should be willing to reciprocate in the other direction if necessary, but this cannot be made peremptory: charity or acts of charity cannot be imposed, as they lose their original meaning. Other authors are of the opinion that the priority for receiving an organ as a measure to increase the number of potential donors is inadequate, since it uses fear as a pressure measure to prevent people from registering in the National Non-Donor Registry, i.e. it limits their autonomy and indirectly manipulates their free choice [15].

Let us imagine that a person who is transplanted with an organ expresses his or her will during life not to be a donor. There seems to be no moral reason that would oblige us to accept such a will. The vast majority will probably find it intolerable that the State should protect this extreme form of selfishness. [14]

As far as social justice and the correct distribution of health resources are concerned, first of all the economic issue is guaranteed, everything is paid for by the health system (procurement, interventions, transfers, etc.) and on the other hand there is no financial remuneration for the donor's relatives. After all, when analyzing the purpose of the moral act, the answer is only one: to save the life of patients who, if they do not receive the organ, will surely die. Organ transplantation is an act of true altruism, it is authentic solidarity for the benefit of others, in a disinterested way without expecting any financial incentive.

2) Social implications

The historical evolution of the donation law has brought with it a series of social changes with respect to this issue and also an interest of professionals and scientists to investigate some of the factors that influence organ donation and non-donation in Chile, both at the personal, family and community level.

To begin with, we could assume that religions, particularly Catholicism, accept organ donation and promote it as an act of altruism, in a context of maximum ethics. However, some studies indicate that paradoxically, many of the faithful are unaware of this criterion or misinterpret moral teachings and reject donation. In Chile, religious reasons are the reason for family refusal of organ donation in 10% of potential donors. Among the reasons, they refuse donation because of fear of apparent death and rejection of mutilation of the corpse. The position of the Catholic Church: it advocates a fairer distribution of organs and sees the human being in the face of life not as the absolute owner of his body, but as the receptor of a divine gift which he has to administer. [16]

Another point of study is that the shortage of organs is due to the inability to convert potential donors into effective donors and not to an actual lack of donors. In fact, international experience shows that the application of the presumed consent model alone is not capable of increasing the number of transplants. In this regard, it is important to highlight the importance of the Spanish model, the country with the highest rate of donors per million inhabitants, in terms of the qualities of the working team, which has been described as proactive, skilled, highly motivated, with administrative support and subject to management control mechanisms to ensure transparency and quality of results. This gives public confidence. With respect to educating the population, young people seem to be the segment of society in which the campaigns would have the greatest return, as they are in a period of learning attitudes and values, showing great interest in knowing the testimony of those who have been transplanted.

In a study of The Media in the Process of Organ Donation in Chile, 64.7% of those interviewed acknowledged that they were informed, 27.5% said they were not informed. While 90.2% of respondents tended to want more information on organ donation and transplantation, and an equal percentage agreed that more and better information would encourage more organ donors. It is concluded that people consider themselves informed and that their main means of information is television; although they think that they have made their decision with the necessary information, it seems to them that more and better information would increase the number of donors. This study only measures people's perception of their knowledge, but does not assess whether that knowledge is correct and in line with the terms proposed in the law. [17]

In Chile, some studies indicate that organ donation behavior is favored by knowledge of the experiences of third parties, solidarity and convenience (of the person or a family member needing a transplant in the future), while those who are not willing to donate organs do so for fear of outcomes (mutilation of the body, "fear of what their body will look like after organ extraction", fear of thinking about death and early disconnection) and lack of information. [18]

In relation to the factors or reasons that would make non-donors change their minds, in another survey, those involved acknowledged that the most important factor is "saving the life of a family member". On the other hand, the person who can positively influence the decision to donate organs is the trusted physician of the potential donor. [19]

On this last point, it should be emphasized that the training of the health care team and their personal vision on the subject will have a direct influence and will be of great importance for the decision of donors and their relatives. It is not only important to educate the general population, but also the health team. The approach to the family should not be limited only to the moment of signing documents, because for them the donation process begins the moment they are informed that their family member will die. Family members are zealous evaluators of the care received, empathy, timely information and recognition of the patient's preferences, so the health care team's efforts should be geared towards meeting these needs. [16]

Another study of psychosocial determinants of organ donation intention in a Chilean sample concludes that a positive attitude towards donation, influenced by body-related concerns and knowledge about brain death, predicts organ donation intention, as well as social influences and family discussion. The results show that people who have clear and accurate knowledge about brain death tend to have a more favorable attitude towards donation and a greater willingness to engage in family discussion. This discussion is often negatively influenced by the anxiety and rejection produced by topics related to the corpse and death, which causes people to avoid getting involved in this type of conversations, in which the taboo connotation of death and the corpse still has an important weight in our country. Finally, bodily apprehensions also stand out for their negative effect, such as concerns related to the manipulation of the body and the consequences of organ removal, with results consistent with those of other studies. [20]

3) *Clinical implications*

Although in the course of the history of the donation law in Chile, it has undergone important changes in terms of presumed consent and the registry of non-donors, to name a few, some questions arise that need to be clarified. The following is an extract of information from the Ministry of Health:

"Is the family of the deceased always asked about organ donation? Yes. Organs are never removed from a person without first talking to the family about their last wishes and having them agree to sign the legal documents to proceed with the donation.

What happens if the family objects to the donation? If the family objects to the donation, even if the deceased has expressed his or her will to be a donor during his or her lifetime, the decision of the bereaved is respected. That is why it is important to discuss this issue with the family, as in many cases it is ignorance or doubt that leads to the family's refusal". [21]

This casts doubt on the effectiveness of the measures taken by the government, in terms of the changes included in the Donation law. Data on donation and transplantation in recent years are shown below. [22] [23]

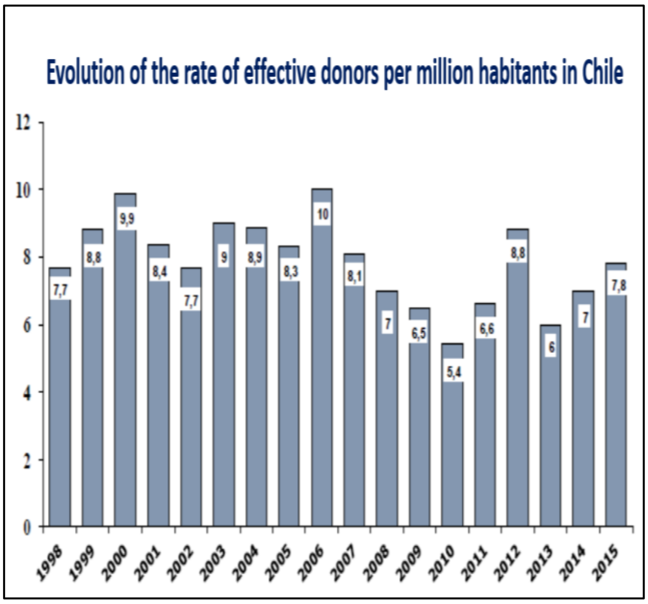

Fig. 1. Graphic about the evolution of the rate of effective donors per million habitants in Chile

An inconsistent rate has been maintained despite new legislation, at approximately 8.4 donors per million people.

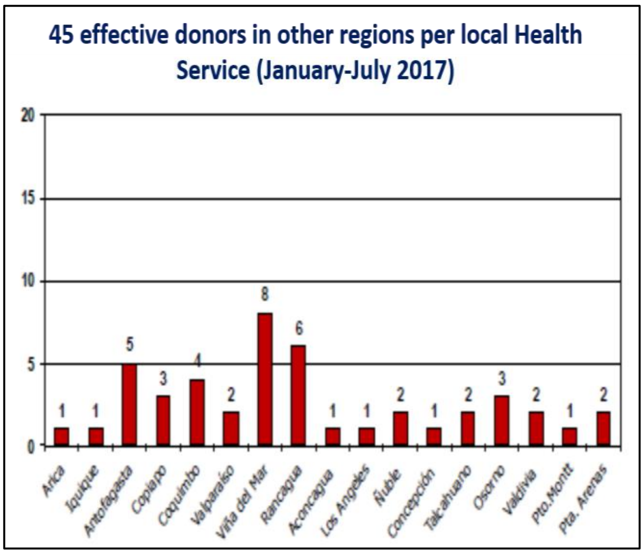

Fig. 2. Graphic about demographic distribution of organ donors in Chile

In the last period of January-July 2017, of the 109 organ donors in total, 49 effective donors correspond to the Metropolitan Region and 45 effective donors in other regions, of which only 1 donor comes from the Concepción Health Service and 2 from the Talcahuano Health Service.

In addition, according to numbers from the Civil Registry, a total of 3,907,385 people have registered as non-donors in the country (2010 to 2015). Of this total, 3,897,855 people showed their refusal at the time of obtaining an identity card or driving license. [24]

V. CONCLUSIONS

From the historical legal analysis we can conclude that despite legislative efforts to keep pace with the scientific development of medicine in the field of transplantation, no effective legal measure or method has been found to increase the number of donors, whether living or cadaveric. One of the theories put forward is that the general population is misinformed about these legal issues, and we also consider it important to highlight the prejudices that people have in this matter, which arise from the inadequate way in which this issue has been handled by the different actors involved.

One of the measures we propose to solve the problem is to put more emphasis on informing the general population about the donation process, its legal connotations and the therapeutic benefits that the use of transplants means for thousands of Chileans who are in a situation of loss of health.

We have also observed that despite the legal modifications that have taken place over the years, it has not been possible to resolve issues such as the effective application of the consultation when performing formalities such as driving licenses or identity cards. We have noticed that despite the fact that it is expressly stated in the law that it is the task of the Civil Registry officials or municipal officials who carry out procedures such as renewing an identity card or obtaining a driver's licence, in practice this is not done in all cases. This makes it difficult to obtain reliable information about the wishes to be a living donor and increases the possibility that there may be doubts about being a donor at the time of the person's death, leaving the decision at the mercy of the family's wishes, thus taking away the person's autonomy.

If this is the case, we postulate the need to train the personnel in charge, so that they can apply the consultation in the best possible way and also be able to act as informative bodies for the general population.

Since its beginnings, organ donation and transplantation have been subject to a series of questions raised from a bioethical point of view, and have always been a highly controversial topic of debate from the different perspectives that may arise in this discussion.

Regarding the implications of the law in force today in our country, one of the main questions is centred on the presumed consent to donation, some say that the altruism that frames this fact should prevail, others are defenders of the principle of patient autonomy, in any case, the possibility provided by the law to declare in various ways the refusal to be a donor subject preserves this principle.

At present, the law proposes a distribution system subject to a large number of variables, the main objective of which is to ensure a fair prioritisation of patients who are candidates to receive a transplant. Despite the thorough evaluation and the series of requirements of this selection system, it is not exempt from bioethical questions, as its considerations include not only clinical and biological facts, but also include in its last consideration a statement subject to ethical and moral discussion. The latter implies the eventual need to further objectify the allocation of organs, but even so, we could eventually find ourselves in situations where the aspects considered are raised with the same characteristics in more than one patient, which leads to questioning this need.

Some question the fact that there is no material or economic retribution for the donor's family or the donor himself if the procedure is performed during life. This discussion is one of the least important, as the act of donating is in itself an altruistic and disinterested act, which should provide a retribution beyond the economic aspect, which contemplates the satisfaction of helping others with an action of such a great dimension that succeeds in saving a life.

In the debates that take place in the social framework, the religious stances of the population play a fundamental role, as their beliefs have a great influence on the stance they take on donation, and are also governed by the stance adopted by the institution that heads the religions. In this sense, the relationship that can be established with the top management of these institutions is of great importance for progress in matters of donation.

On the other hand, there is evidence to show that education of the population greatly favours participation in the donation debate, and helps citizens to take a stand. It is not only important to educate, but also to do so with the right information, which will allow each individual to make decisions from a more complete and objective perspective. The relationship that the treating team establishes with the potential donor and/or his/her family plays a transcendental role in the decisions that will be made, establishing a relationship of trust will favour the influence that can be had over the patient and his/her family. In this sense, it is of vital importance to reinforce the different skills of the multidisciplinary team in the field, not only from a biomedical and clinical point of view, but also from a social and psychological perspective.

The new legislation has not clearly favoured the increase of donors, in fact a large part of the population has declared their wish not to be a donor, therefore from a clinical point of view there have been no major advances in recent years, which leads to questioning the effectiveness of the different modifications that the law has undergone in recent years, and raises the need for new interventions with respect to it.

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