

Situation of organ donation and transplantation in Bolivia**Situación de la donación y trasplante de órganos en Bolivia**

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Abstract

After having accomplished an observation of the different problematic that affect the daily life of our city, as reflect of what happens in the rest of the national territory, we have been attracted to implement a juridical analysis to the situation of the donation and organ transplantation in the legal ambit of our country, with the objective to identify the level of efficacy and the normative scope with respect to the situation of people who need a transplant. This restlessness born from the analysis of the law 1716 and its regulation, which ambiguously delimits the functions of the centers of health in what respect to this topic, also to establish the creation of a waiting list and a record, tool which objective would be norm the permanent supply of organs through donation programs. These do not accomplish their objective or being attached to a public policy in the ambit that allow the continuity of the institutions and benefit of the people in need.

Donation, Organs transplantation, List of national waiting, Regulation

Resumen

Luego de haber realizado una observación de las diferentes problemáticas que afectan la vida cotidiana de nuestra ciudad, como reflejo de lo que sucede en el resto del territorio nacional, nos hemos visto atraídos a implementar un análisis jurídico a la situación de la donación y trasplante de órganos en el ámbito legal de nuestro país, con el objetivo de identificar el nivel de eficacia y el alcance normativo respecto a la situación de personas que necesitan un trasplante. Esta inquietud nace del análisis de la ley 1716 y su reglamentación, la cual delimita ambiguamente las funciones de los centros de salud en lo que respecta a este tema, además de establecer la creación de una lista de espera y un registro, herramienta cuyo objetivo sería normar el suministro permanente de órganos a través de programas de donación. Estos no cumplen su objetivo ni estando adscritos a una política pública en el ámbito que permita la continuidad de las instituciones y beneficio de las personas necesitadas.

Donación, Trasplante de órganos, Lista de espera nacional, Normatividad

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Introduction

Scientific and technological advances have changed the life of humanity, becoming an essential part of the development of people's lives, from the use of these advances to carry out simple activities, to being able to benefit from the health of an illness that in another era may not have had a solution, through medical procedures that allow the replacement of a diseased organ with a healthy one.

However, the practice of these procedures includes a series of essential characteristics, among them, the existence of people willing to donate an organ in favour of someone who needs it; the means that will allow the development of the medical procedures necessary for the success of these practices; the existence of the necessary resources, and the fact that these are within the reach of any person.

Bolivia entered the transplant era in 1948 with the first cornea transplant performed by Dr. Javier Pescador in the city of La Paz, followed by a kidney transplant at the Hospital Obrero No. 1 in La Paz in November 1979 by the team of Dr. Néstor Orihuela Montero. Néstor Orihuela Montero, in the following years several transplants were performed, but these were not regulated by any law until 5th November 1996, when the first Law of Transplantation and Donation of Organs, Cells and Tissues came into force; A year later, a Supreme Decree N°24671 that regulates the law N°1716 came into force on 21 June 1997. Since then, more than a decade would pass before the issue of the regulation of transplants and donations was taken up again, On 21 December 2011, Supreme Decree N°1115 came into force, abrogating Supreme Decree N°24671, which became the new regulation for Law N°1716 on Organ, Cell and Tissue Transplantation and Donation.

Organ transplantation in Bolivia is lagging behind in comparison with other countries. There are many reasons why our country does not currently have a relatively acceptable level of progress in this area, mainly due to the lack of material resources and specialised professionals, in addition to the lack of health policies in this area on the part of the State, which is detrimental to the people who would benefit from these procedures.

Although the Political Constitution of the State recognises the right of all people to health, to access the health services they need free of charge, and establishes the responsibility of the State to guarantee the continuity and quality of these services at any level of health care.

The Law on Organ, Cell and Tissue Donation and Transplantation, the main legal instrument that regulates these procedures, lacks a clear and specific determination that would allow access for all those in need. Among these difficulties are, for example: the lack of material and human resources to guarantee the continuous and optimal functioning of the institutions that should be in charge of the administration of these procedures, and even the lack of clear and specific delimitation of the institutions and the powers that correspond to them.

Research is needed to show the current situation of people in need of a transplant, the procedure to be followed to be considered recipients and the characteristics that are taken into account for their consideration as such, according to the law.

The legislation regulating the transplantation and donation of organs, cells and tissues in our country does not work effectively for the benefit of people in need of transplantation due to its lack of specificity and the lack of regulations for the institutions that would be responsible for carrying out these procedures. The ambiguity that exists within the Law on Organ, Cell and Tissue Donation and Transplantation can be considered a detriment to both the voluntary donor and the potential recipient. The lack of management and bureaucracy of the institutions violate the right of potential recipients and donors.

Implementation of the corresponding legislation by the institutions in charge. In this sense, the present research work was carried out in three stages:

- Bibliographic and documentary review of national legislation in this area.
- Collection of data on the reality of the functioning of the institutions in charge of organ transplantation.

- Verification of the existence of legal resources that enable health centres to carry out organ, cell and tissue transplants.

The application of laws and special laws for organ donation and transplantation that ensure the correct participation of the state, the entities of the branch, and the population in the design of public policies.

The State should promote the coordination of health institutions, as the costs of transplantation are very high, dividing the functions: analysis, patient preparation, surgery, etc. This is another way of reducing the cost of transplants.

The state should disseminate information about the access to the national waiting list and the special registry for potential donors and recipients to the population, and raise their awareness. This is a voluntary and altruistic act.

It is necessary to train health officials on the issue of the single national waiting list and special registry for potential donors and recipients, as the knowledge of public officials is limited, Training is not only of benefit to health officials, but would also help people who need data on this topic.

The state should create support policies for Bolivians who need transplants and who do not have the necessary economic resources to be able to pay the cost of a transplant. This could be done by creating a fund for this purpose: from taxes, resources from the municipalities, prefectures, and thus be able to improve the quality of life of the people.

The state should control the resources and supplies that it gives to health institutions, since many of them do not reach the patients.

It is vitally important to create web pages for greater accessibility to the registry of potential donors and recipients. An example that should be followed is that of Panama, a country whose registry is on the internet and is carried out through the same means, to acquire the donor card, the volunteer registers his or her data online and must only pick it up at the office in charge of donations and transplants, a quick and efficient way of handling the special registry for potential donors and recipients.

Conceptual - theoretical framework

Single national waiting list

The waiting list is a database containing all the names and other data necessary to be able to decide on the most suitable recipient for a specific available organ. The most suitable recipient will be determined by various data, and especially by the compatibility of the organ to be transplanted and the donor. This compatibility is determined, without going into the technicalities of immunology, by the blood group, anthropometric dimensions and HLA-DR, HLA-A, HLA-B antigens in the case of kidney transplants.

The waiting lists are different depending on the organ. In the case of heart, lung and liver, it is a centralised list because while the increase in activity in the field of kidney transplantation depends on the local infrastructure and coordination (organ generating hospital as well as other provincial or regional hospitals), the transplantation programmes for non-renal solid organs, liver, heart and lungs will be all the more active the more they are open to the limits of their area and therefore the better the exchange infrastructure they have.

The explanation lies in the following points:

- The lives of people on cardiac, lung and liver waiting lists depend on transplantation.
- The compatibility between donor and recipient is not based on HLA typing, but on blood group compatibility and organ size.
- Preservation fluids do not allow for organ preservation of more than 4-6 hours for the heart and 6-8 hours for the liver.
- The maintenance parameters and clinical conditions that the potential donor must meet differ or increase their requirements.

All of this explains why not all organs generated in a centre in an autonomous community will have a suitable recipient on its own waiting list.

The central office of the ONT (National Transplant Organisation) is responsible for the so-called out-of-hospital coordination tasks or, as we could also call it, the organisational aspects of the donation/transplantation process. There is a group of ONT nurses who, among other functions, are directly in charge of this work. In general, the central office in Madrid is in charge of coordinating donation alerts throughout Spain, with the exception of Catalonia, and the Barcelona office coordinates extractions within the territory of its autonomous community, as well as offers or donations from Spain to other European countries or from other European countries to Spain.

Special register for potential donors and recipients

The primary objective of the register of organ donors is to implement a single register of citizens who have expressed their willingness to donate organs, either positively or negatively, and it is a strictly confidential file through which we can all record our willingness to be a donor during our lifetime after our death.

In the national territory, and with a respective coordinator for each department, a special registry is managed for possible donors and recipients, this registry is based on a book of minutes, which is found in all SEDES health centres, the future donor must pass a series of studies and laboratory analyses, to later form part of the list, the registry is the first step towards becoming a donor.

National legislation and international agreements

In 1989, at the initiative of Dr. Nestor Orihuela Montero from La Paz and Dr. Juan Pablo Barrenechea from Cochabamba, the nephrologists of Cochabamba, the nephrologists of Cochabamba and an outstanding group of other specialists from specialists from La Paz and Cochabamba, founded the Bolivian Society of Organ and Tissue Transplantation (SBTOT). (SBTOT), in order to elaborate the legal framework for the practice of organ and tissue transplantation in Bolivia and to spread the and to disseminate the necessary knowledge about transplantation to the medical profession and the general public the necessary knowledge about transplantation among the medical profession and the general population.

The society worked for eight years in close collaboration with the bioethics institute of the Catholic University of Cochabamba, directed by Dr. Manzanera Miguel S.J., and the Bolivian Academy of Medicine (ABM), on the drafting of a transplantation law and its complementary regulations.

The law was passed in the Chamber of Deputies in January 1992, after many difficulties and stumbling blocks due to political adversity and cultural prejudices of our population. It took almost five years for this law to be approved in the Senate and enacted as Law No. 1773.

Senate and promulgated as Law No. 1716 of 5 November 1996. The regulation was The regulations were elaborated by the transplant society in Cochabamba in 1989, revised and approved by the national by the national society in 1990, by the health commission of the Chamber of Deputies in 1992, and by a special a special commission constituted by representatives of the national health secretariat, the Bolivian medical association, the transplantation society and the Bolivian academy of medicine in 1997 and promulgated as supreme decree No 24671 on 21 June 1997.

Due to the need to update the regulations on organ, cell and tissue donation and transplantation, considering the scientific and technical-operational advances in the practice of procurement, ablation, preservation, storage, transport and transplantation of human organs, cells and tissues, and to strengthen the steering role of the Ministry of Health and Sports and guarantee the quality of care, Supreme Decree No. 1115 of 21 December 2011 was enacted.

Months before the promulgation of Supreme Decree 1115, the tenth meeting of the Ibero-American network/council for organ donation and transplantation was held. Cartagena de Indias (Colombia) 23 and 24 March 2011, where Dr. Olker Calla Rivadeneira was responsible for the renal health programme of the Ministry of Health and Sports of the Plurinational State.

Having reviewed Bolivian legislation, international conventions, meetings and congresses, on a certain point, which is the single waiting list and registry of potential donors and recipients, it should be emphasised that there was already an attempt to regulate, create and modify the list of recipients, only the regional coordinators would have access, adding new registered patients, eliminating those who have already been transplanted or have died while waiting for an organ and/or temporarily eliminating those who cannot be transplanted because they have a temporary contraindication.

Thus, regional coordinators, when faced with the existence of a potential cadaveric donor, choose the best regional recipient from the list according to immunological compatibility, relative urgency, degree of sensitisation and length of time on the waiting list, in order to achieve the fairest and most correct distribution of organs possible, based on solid scientific and ethical foundations and without any possible preference or discrimination.

Comparative legislation

The normative development related to donation and transplantation varies substantially from country to country, with complete, updated and recent legislation, as well as others without normative development other than the statements set out in the general health laws.

In Mexico, Honduras and Venezuela, as of September 2012, there were legislative projects to modify and complement the regulations related to donations and transplants, which will be approved in the next legislature in each of the countries. On the other hand, Ecuador has one of the most recent legislations on the subject, and to date it is still in the process of being approved.

Spain

In the world, Spain heads the list of countries with the highest rate of organ donations, Law 30/1979, of 27 October, on organ extraction and transplantation, a general regulation, however, in Article 7, Paragraph I, the concern that exists on the part of the Spanish government, which not only sought a regulation that would be of benefit to their country, but also incorporates in one of its articles a regulation that would be of benefit to the country.

On the contrary, it incorporates in one of its paragraphs "The constitution of organisations at national and regional community level will be facilitated and collaboration will be established with international entities that make possible the exchange and rapid circulation of organs for transplant, obtained from deceased persons, with the aim of finding the most suitable recipient".

With regard to the regulation of donors or recipients, it is clear that donors may be of legal age, of sound mind and in a state of health adequate for the removal of the organ. In the case of an organ whose extraction is compatible with the donor's life and which does not seriously diminish the donor's functional capacity and is declared, in writing, before the judge in charge of the civil registry of the locality in question, in the case of living persons.

In the case of deceased donors, proof of brain death must be provided. On the other hand, the recipient may express affirmative or negative consent for the transplant, graft or implantation to be carried out, something that is very striking since in Bolivia the only person who can give consent is the donor.

It is important to take into account that Spain is a country that apart from having a higher rate of donations, is a country that is concerned about the dissemination and education of the same, for this reason in the Royal Decree 2070/1999, in Chapter II, Article 6. Promotion and publicity, the health authorities are in charge of promoting the necessary information to the population about the benefits for the recipients, the conditions, requirements and guarantees that this procedure entails, the promotion is carried out in a general way and always remembering that it is a voluntary, altruistic and disinterested act, This is due to advances in technology for the rapid extraction of organs and their preservation for subsequent transplantation, as well as the creation of an efficient and sufficiently agile mechanism that allows immediate judicial authorisation for obtaining organs.

In the study of the Spanish and Bolivian regulations on the subject, the same objective is to substantially improve the recipient's hope or conditions, it is clear that in general the Bolivian regulations have the basics in their rules, it would be very important to take the Spanish legislation as a basis for future rules and/or regulations, as only this does not worry about waiting for donors, on the contrary it is the one that looks for donors not only within its territory but also outside its borders, This is thanks to a system of efficient organisation and, always looking for its legal scope to obtain the respective permits as quickly and efficiently as possible, it is important to mention that Spain with respect to its transplant and donation rules has an important number of regulations that over time have been regulating in more detail to its general rules, it is known that it tries to be in accordance with the medical-scientific updates and this makes the types of donors a little wider, which should be taken into account for the Bolivian rules. for the Bolivian norms.

Ecuador

Ecuador has specific regulations with respect to organ transplantation, something important is the preservation of the health of both the recipient and the donor, which is why Ecuadorian law indicates in one of its articles of its transplant and donation law that "any person who has received an organ by transplant will have preferential treatment in medical care with the aim of preserving the transplanted organ and improving their quality of life. Likewise, any person who, having received an organ transplant, has not recovered his or her functional, organic and/or working capacities, will be considered as a person with a disability, so that he or she can obtain the relevant legal benefits. The same treatment will be granted to any living donor who, due to the effects of the donation, has suffered an alteration that means a decrease or disability in his or her organic functions and health that, duly certified by a qualified medical institution, makes him or her at least partially incapacitated for the activities he or she carried out before the donation", the state is in charge of the care of donors and recipients who have had some complication with their health, after the intervention carried out.

It is important to have a document that indicates that a person is a donor, Ecuador no longer uses a main document, donors have the quality of donor or non-donor inscribed in their identity document, it is regulated by the national law of that country "The manifestation, restriction or conditioning of the will for the donation of anatomical components will be made

The manifestation, restriction or conditioning of the will for the donation of anatomical components will be stated in the citizenship card in the case of Ecuadorian citizens and in any other identification document in the case of foreigners legally residing in the country".

Once the death of a person has been verified and certified, all or part of his or her organs, tissues and/or cells may be disposed of. In case of violent death of a person, the removal may only be carried out when it does not interfere with the final results of the autopsy, being necessary for the performance of the ablation of organs and tissues the prior notification to the public prosecutor on duty.

The normative development related to donation and transplantation varies substantially from country to country, with complete, updated and recent legislation, as well as others without normative development other than the statements set out in the general health laws. In Mexico, Honduras and Venezuela, as of September 2012, there were legislative projects to modify and complement the regulations related to donations and transplants, which will be approved in the next legislature in each of the countries. On the other hand, Ecuador has one of the most recent legislations in signature and to date most of the regulatory frameworks date back several years, which in some cases means that technological advances are not contained in them or have had to be regulated by decrees or annexed resolutions without correlation, a situation that generates difficulties when establishing which is the current regulation for a particular topic.

The World Health Organisation's guiding principle 6 establishes that each country should promote the altruistic donation of organs, tissues and cells; however, it was found that this stipulation has not been included in the majority of Latin American legislations.

Among the countries that include practices for this type of promotion are Brazil, Colombia, Ecuador, Panama, Venezuela and Spain, whose legislation includes, among others, the promotion of donation in free or state-funded campaigns and the order to include information about the benefits, importance and necessity of donation in the curricula of primary, secondary and higher education.

Research Methodology

Methods

In order to obtain and collect comprehensive, complete and up-to-date information, the following quantitative, but mainly qualitative research methods and techniques were used, as the latter is considered to be a social science method.

Quantitative

As it is an effective method for accurately describing economic, political and social data. We also used it to interpret this information, having used the following techniques:

- a) The survey was applied to a general population sample. Between 14 and 52 years of age.
- b) Statistics: This allows us to graphically detail the data obtained in the surveys. They are as follows:

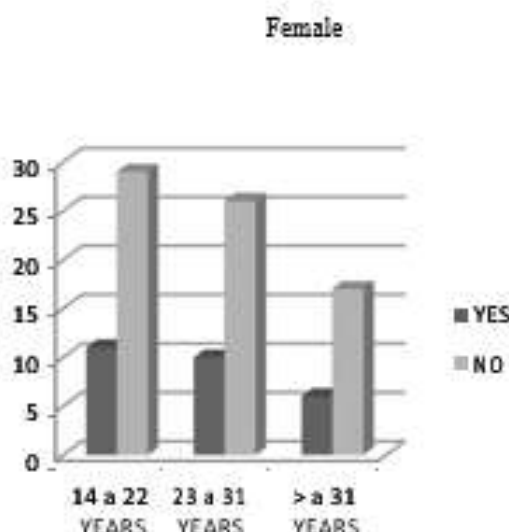
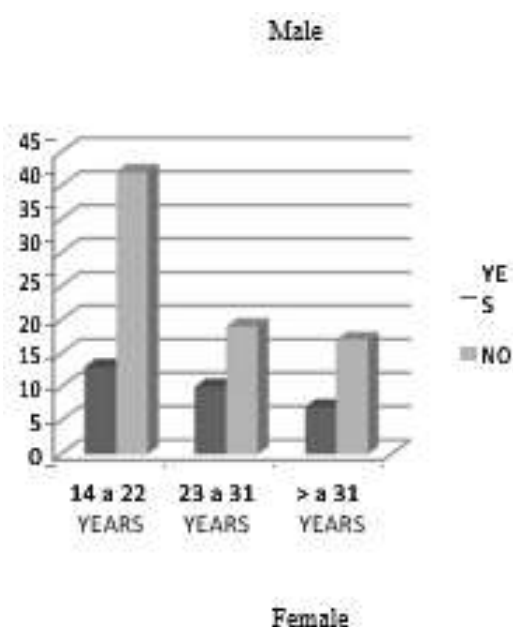


Figure 1 Would you be willing to donate any of your organs to someone you do not know - while you are still alive?

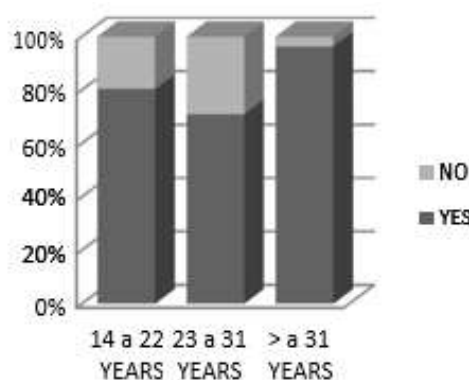


Figure 2 Would you be willing to receive another person's organ if you needed it?

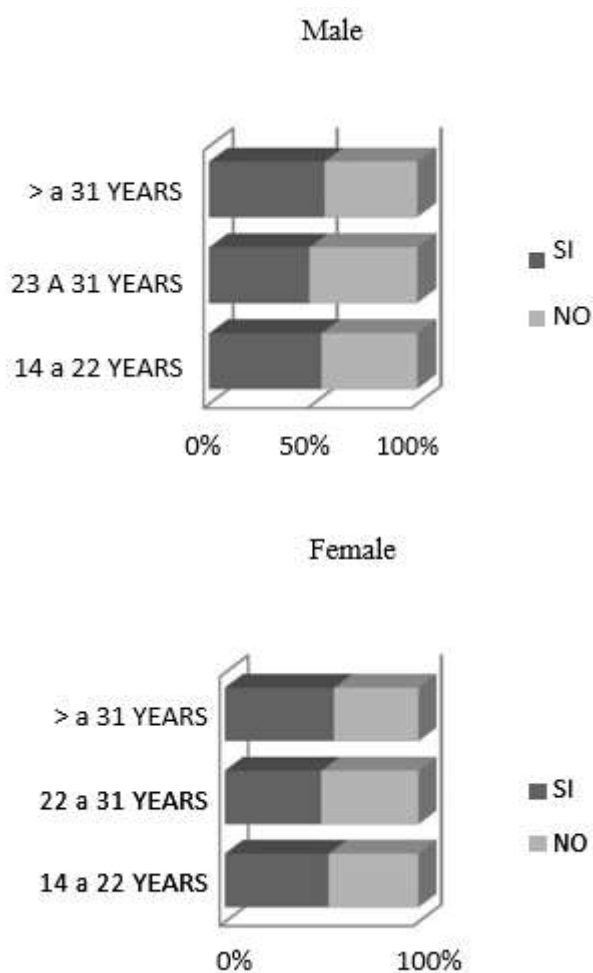


Figure 3 Would you allow the organs of a loved one to be donated?

These tables show similar results to those obtained in question 7, taking into account the nature of the question. People of both sexes in the younger age group are more unaware of the Special Register for Potential Donors and Recipients. However, awareness rates are not higher among the older age group.

Results obtained

The Political Constitution of the State protects the right to health, as stated in Article 45, paragraph 1° "the state at all levels shall protect the right to health by promoting public policies aimed at improving the quality of life, collective well-being and free access to health services for the population". Article 43 states that "the law shall regulate donations or transplants of cells, tissues and organs under principles of humanity, solidarity, opportunity, gratuity and efficiency". Article 37 "The state has the undeniable obligation to guarantee and sustain the right to health, which constitutes a supreme function and the first financial responsibility".

Within the framework of Bolivian legislation, there is only law 1716 on organ, cell and tissue donation and transplantation, supreme decree N° 24671 on physical infrastructure, and the law on the provision of health care services.

This was abrogated by Supreme Decree N° 1115 that regulates Law 1716 on Organ, Cell and Tissue Donation and Transplantation, establishing the scope of application, the organs, cells and tissues that can be donated, the categories of donors, recipients, functions and obligations of health establishments and professionals involved in organ, cell and tissue donation and transplantation.

The law on organ, cell and tissue donation and transplantation regulates organ donation and transplantation, mentions the characteristics that a donor must possess, whether a living donor or cadaveric donor, and states that it is necessary to be registered in a register of potential donors and recipients, but does not provide information on the procedure that the volunteer must follow in order to belong to this register,

With regard to the single national waiting list, Supreme Decree N° 1115, which regulates Law 1716 on Organ, Cell and Tissue Donation and Transplantation, states in Article 15 "The Departmental Transplant Coordinator will register the cadaveric donor in the single national waiting list, administered by the Ministry of Health and Sports, for the distribution of organs, cells and tissues among the registered recipient patients, using the criteria established in the manuals and protocols in force".

It can be seen from the surveys that a large percentage of those surveyed are not willing to donate an organ while alive; on the contrary, there is a greater acceptance of organ donation after death, and a high percentage are unaware of the single national waiting list, as well as the special register for potential donors and recipients, and how to access it.

It is very clear that the authorities of the health care institutions are not aware of the single national waiting list and the register of potential donors and recipients, due to the lack of information from the institutions in charge of the dissemination of information concerning the state.

In comparison to other legislations, the national legislation is not fully specified in some aspects, but it does have a detailed regulation referring to the administration of health institutions and the management and care to be followed by the personnel in charge of transplants. In the financial aspect, the state, as indicated in the regulations, must do everything possible to provide a quality service, but it is difficult to cover the needs of the entire national territory, which is why some institutions are semi-public and semi-private, in order to cover the expenses and needs they have to cover.

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Discussion

Bolivian society still has a certain fear regarding organ donation, even more so when it comes to donating organs during life. It is also important to highlight the existence of regulations that regulate organ transplants, but there is a vacuum within the same regulations regarding the single national waiting list and the special registry for potential donors and recipients, in comparison with other countries, where access and information is provided to belong to the same, one of the factors is the lack of dissemination of the regulations, which generates ignorance of the single national waiting list. The special registry for potential donors and recipients is only mentioned in the regulations in general terms, and the people in charge manage this registry in a book of minutes that exists in each department.

The state is responsible for dissemination policies, but the state's efforts to raise awareness are not sufficiently effective. The need to obtain a donor leads to the extreme of buying the organ needed by the recipient. There is a small contradiction with the law, which does not allow the purchase of organs, nor does it allow any kind of publicity regarding the sale or purchase of organs.

Conclusions

Unfortunately, the subject presented by this project has not yet awakened a solid and real interest in the competent health authorities, because as we have seen, there is no specific regulation that could make it known to the competent authorities.

The issue presented by this project, unfortunately, has not yet awakened a solid and real interest in the competent health authorities, because as we have seen, there is no specific regulation, which could give exact information about the single national waiting list and the special registry of potential donors and recipients. On the positive side, we highlight that there is a legal regulation in force that regulates organ transplantation, but as a deficiency, we note that this law does not regulate or make known a procedure that should be followed by volunteers who are living and/or cadaveric organ donors in order to enter a registry of possible donors, which is also a weak point for the recipients, since the same procedure is not found in the regulation.

Another positive feature is that the law and its corresponding regulations have the function of informing, informing and creating an awareness of humanity in society, as well as the dissemination should be the responsibility of the Ministry of Health and Sports and the entities that are governed by the same, in the case of treaties and agreements signed on transplantation issues, the Ministry of Foreign Affairs is in charge of this.

The management and use of the single national waiting list and the special register for possible donors and recipients should be carried out taking advantage of the latest computer technologies, there would be a better management of the data, both of the recipients and of the patients, in the national territory, at present we highlight a deficiency since this register is incorporated in a book of minutes, which does not speed up the exchange of data between departments.

These interviews demonstrated a lack of knowledge on the part of the authorities and directors we interviewed in health institutions about the existence of and access to the single national list of potential donors and recipients, On the contrary, they showed interest and provided some ideas about future projects that the State should undertake to adapt and update the facilities and at the same time improve organisation and cooperation between health institutions so that in the future a better service can be provided and patients can have access to organ transplants not only in the cities of La Paz, Santa Cruz and Cochabamba, but also in other parts of the country.

The surveys made it clear that there is a need for early socialisation and dissemination of information about donation and transplantation, a single national waiting list and a special register for potential donors and recipients, as this issue is of great importance because it deals in some way with people's lives as a legal right to be protected.

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