

Bioethical aspects of organ transplantation. A comparative study between Spain and Mexico

Aspectos bioéticos acerca de trasplantes de órganos. Estudio comparado entre España y México

Ulises Pacheco-Gómez^a, Itzel Pacheco Navia^b

Abstract:

Loss of life with signs of cardiocirculatory death or brain death are relevant aspects to decide organ transplants, thus in many cases, it is desirable to obtain those organs from deceased patients, although it is always available the option if the patient is alive. Because of that, the following article shows a compared study between Spanish and Mexican Laws concerning some bioethical aspects considering organ procurement, informed consent, deceased or living donation, paired donation, confidentiality, and criminal issues.

Keywords:

Bioethics, Law, Loss of Life, Transplants

Resumen:

La pérdida de la vida, sea con signos de muerte cardiocirculatoria o de muerte encefálica son aspectos relevantes para la decisión sobre el trasplante de órganos, pues en muchos casos es preferible obtenerlos de pacientes cadavéricos, aunque siempre está la opción de que el donante esté vivo. El artículo plantea un estudio comparado entre la legislación española y la mexicana, en relación con algunos aspectos de carácter bioético, considerando la obtención de los órganos, el consentimiento informado, donación cadavérica o intervivos, donación cruzada, confidencialidad y cuestiones sobre tipos penales.

Palabras Clave:

Bioética. Legislación. Pérdida de la vida. Trasplantes

INTRODUCTION

This article will study the bioethical aspects of organ transplants. The definition of loss of life within the signs of cardiocirculatory death, or brain death, is of great relevance and referred to as transplants, so organs will be obtained preferably from people who have lost their lives.

On one hand, it is not the only way to get organs, thereby they could be gained from an alive person. Its common term is the corpse in both Mexican and Spanish regimes.

On the other hand, the consent policy and its criticism will be checked.

Keeping in mind that Spain represents 20% of the donors from the European Union, as a result, World Health Organization designated National Transplant Organization as the organism which controls donations worldwide.

In Mexico, a low organ donation rate is one of the motives for having a low number of transplants. Even during the last few years, the donation of organs and tissues campaigns increased, the country has an average of 4.5 contributions with brain death per every million inhabitants.

^a Ulises Pacheco-Gómez, Autonomous University of Hidalgo State, <https://orcid.org/0000-0003-0984-7876>, Email: ulises_pacheco@uaeh.edu.mx

^b Itzel Pacheco Navia, Autonomous University of Hidalgo State, <https://orcid.org/0009-0008-9423-7127>, Email: pa351986@uaeh.edu.mx

ORGAN PROCUREMENT FOR TRANSPLANTATION

Both in Spain and Mexico, deceased and living donations are recognized. First of all, regulatory features will be taken into consideration from deceased donations.

In Spain, Royal Decree 1723/2012 mentions that deceased donations start diagnosing death, both by brain death or by cardiocirculatory death, known as asystole donation (Pérez, 2015).

While in Mexico the process of donation is a shorter term than that in Spain, hence it must be certified that the donor has lost his life, observing the regulations established by the General Health Law and its Regulations on Transplants.

Firstly, selecting a deceased donation requires a medical evaluation, which will be verified with other data that it must have had the required psychological age to donate in the moment of loss of life. Secondly, not having presented malignant neoplasms with a risk of metastasis, infections, or other conditions that might affect the receiver. Lastly, not having suffered the deleterious effect of prolonged agony.

As stated before ahead, in Spain exists an uncontrolled asystole donation. In 1997, the American Medicine Institute stated the criteria of cardiocirculatory death means no pulse, which needs confirmation via Doppler. There are two types controlled (DCD) and uncontrolled (uDCD).

The main difference focuses on the place where the death occurred. On one side, a controlled one is always produced in the Intensive care unit. On the other hand, uncontrolled one occurs outside the hospital (Tenza et al, 2017). The uncontrolled Europe Union is only practiced in Spain and France since the strict protocol, due to death outside the hospital. First, after resuscitation maneuvers were performed and were declared unsuccessful after 30 minutes, the person will be transferred to a hospital. In the period of arriving at the Care unit, some maneuvers of preservation must be considered:

- Compressing
- Access
- Intubation

Once the patient is admitted to the hospital, the physician is in charge of giving a death certificate. Furthermore, in case of not finding any relative, it is asked to the duty court through remote communication to perform more invasive preservation maneuvers for future transplants. After 15

minutes without having an answer from the jury, the answer is seen as positive, and exercises are done, for example, heparinization, cannulation, and installation of an extracorporeal circulation membrane or ECMO. Afterward, the patient's family members are localized and are questioned to permit to perform the transplant.

As stated before, there are few places over the world where this protocol is done. In Mexico, uncontrolled donation is not implemented, only controlled ones; however, it is not a common practice in our country. The results in terms of living of asystole donor's organ transplants have been demonstrated to be acceptable for kidney and lung transplants. At this moment, the question arises, what does Mexico need to conduct these types of donations? Perhaps better training is needed to do the Internal Transplant Committee in diverse hospitals, do simulations of uncontrolled donation, and analyze which weaknesses and strengths.

INFORMED CONSENT

Informed consent is a legitimizing criterion to dispose of the human body for transplanting. (Pacheco, 2011).

In Mexico, according to the established-on articles 321, 322, and 324 of the General Health Law, the consent can be:

- Tacit: there is no negative answer to dispose of the organs and tissues after death.
- Express: this manifestation of consent must be done in a written and oral way, and vice versa. Referring to the organs of disposition will be classified into total or partial, and the last receiver.

In Spain, Royal Decree 1723/2012 establishes that the obtention of deceased donor organs with therapeutical purposes could be done if the deceased whose organs are intended to obtain has not expressed his opposition to taking his organs after death, viewed as a Tacit disposition. In this situation, resistance and conformity must be stated, referring to the totality of organs or only some.

As we can see, it is an easy process, which means that if the deceased does not express his desire not to be a donor, his organs can be used to help patients waiting for a transplant. Therefore, Spain is considered the main country with the potential for transplanting.

Conversely, in Mexico, the General Health Law states in its article the following:

“ There will be tacit consent of the donor when he has not declared his negation to his body or components used for transplants, provided that there is consent in whatever of the

following people who are being presented, for instance, the spouse, the concubine, the descendants, the ascendants, the siblings, the adopted or the adoptive.”

“The writing in which a person exposes his motives of not being a donor is private or public and must be signed by this person. The negative answer may be recorded on any of the public documents to determine Health Secretary, the purpose in coordination with other competent authorities.”

The difference between Spain and Mexico regarding consent is that in Mexico, the Law demands that even when the deceased does not show his negation, the donation can be approved by relatives. Meanwhile, in Spain, the approbation of the relatives is not needed unless referring to underage or disabled people.

BRAIN DEATH

The publication 1995 of the Guides of the American Neurological Society explains the criteria for brain death (Varelas et al, 2010). The essential aspect to know is that there are preconditions to fulfill before starting a neurological exploration of the patient, as the following:

- Body temperature above 35 C°.
- Not having a disease of any kind of endocrine system.
- Not having an extreme hydro electrolytic alteration.
- Not to be under defects of any drug or central nervous system depressant agent.

Once the previous characteristics are verified, it continues with the neurological exploration, proceeding with the scale of Glasgow¹ to explore the level of consciousness or coma that a person shows. The next step focuses on the examination of the brainstem, carried out in two ways:

- Apnea Reflex

Supply atropine, 0.04 mg/kg, if the brainstem does not respond to the stimulus of atropine, in other words, it is abolished.

DONATIONS BETWEEN THE LIVING

The donation within the living has various issues to analyze. Nevertheless, it is estimated that one of the best important is the expression of informed consent, hence is related to the disposition of a vital part of the human body.

Corresponding to the first issue, it will be revised into three fundamental aspects:

1. If informed consent is a necessary condition and enough to perform the living donation.
2. Differentiate among those assumptions that facilitate the potential, including or not considerations about the receiver's organ.
3. Peek the level of assumable risk on the part of the living.

Firstly, in Spain, to perform the living donation must be collected a previous report from the Ethical Committee of the Hospital where the transplant takes place. In addition, the juridical intervention is within a record of voluntary jurisdiction. These requirements aim to ensure that the voluntary principle is achieved, as well as altruism on the part of the living donor. The second feature that distinguishes the regulation of informed consent is the living donation, the information facilitates the potential donor about the receiver, particularly about the possibilities of success of the transplant.

Royal Decree 1723/2012 was in charge of specifying that the living donor can not be life-threatening his life with the donation. In the same case is forbidden that underage donates living organs except for bone marrow, or it could be beneficial for any sibling.

Based on Mexico, stated in the Regulation of the General Law of Health on Transplants is foreseen in article 25 that in the cases of the living donors' transplant, once the Internal Transplant Committee has evaluated favorably not only the donator but also the candidate receiver, it must be given the necessary information to the National Transplant Registry through its computerized system before transplant.

In the case, the donor does not have a blood relationship with the Internal Transplant Committee of the health facility where the transplant will take place, a favorable resolution must be previously issued to the registration of the candidate receiver in the National Transplant Registry.

When the donator or receiver has foreign nationality, this resolution will be signed by all the members of the Internal Transplant Committee. It can be observed that both countries in charge of the decisions will be the Internal Committee or the Ethical Committee looking for the greater well-being of the donor and the receiver.

¹ According to Muñama-Rodríguez and Ramírez-Elías (2014), the Glasgow Scale is an internationally recognized tool to assess a

patient's level of consciousness, in 2 aspects, alertness, and cognitive status.

PAIRED DONATION

In the living donations, there are related and non-related donations. The first one, the related one, is explained by Mexican Law when the donors are relatives of the receivers.

Guiding principle number 3 of the Secretariat's Report about organs and human tissue transplants (World Health Organization, 2009) recommends that living donations are always related. In other words, the receivers are related people to genetic relationships.

Concerning non-related donation, the law allows the possibility of a living transplant which in the last years has been carried out with excellent results. On one side, they are called paired donations. On the other side, they start with a good Samaritan.

The cross-kidney transplant is a procedure first described by Rapaport in 1986 and published in the magazine Transplantation Proceedings. The idea of this type of donation is to cross donors with receivers.

In the paired donation, donors and receivers are not suitable for a transplant. Even when the donor of each pair is suitable to the receiver of the other. Meanwhile, donors and receivers express their willingness, and the physicians could evaluate the procedure of pair donation.

The first pair donation was in South Korea, in 1991, and the second in Suize in 1999. It was not until 2009 that pair donation was performed in Spain, the previously mentioned year. It was the first cross-kidney transplant that happened separately in the hospitals Virgen de las Nieves de Granada and Clinica de Barcelona.

One of the biggest pair donation chains implies that containing more links of the chain so far was accomplished over a long time. In the initial months of the year 2012 in the United States. A chain had an early link to the chain in California, representing the good Samaritan, the name Rick and the last name Ruzzamenti, and which had the last relationship with the chain in Illinois, represented by the kidney patient Donald Perry.

The longest chain achieved until now was done in Spain, which involves six transplants and the participation of five hospitals.

As requested by press release No. 380/2017 from the file of the Mexican Government (Mexican Social Security Institute,n.d), the paired transplant has been practiced since

1996 in the High Specialty Medical Unit, Hospital de Especialidades No. 71 de Torreón Coahuila, 153 surgeries of this type have been done whose purpose is to resolve the incompatibility that has with the donors. Donate an organ to another person, and know that the relative will be benefited in the same way is seen as “double altruism” claimed by the director of Hospital General de La Raza.

This option causes a new expectancy of life which changes receivers' perspective since they do not have to remain on the waiting list of deceased donors. Finally, this choice offered to the patients materializes transplant.

CONFIDENTIALITY AND PUBLICITY OF THE DONATION

Corresponding to the aspect of the law with the living donation are that taking into account countries and systems, which are based on confidentiality, publicity, and promotion of donating.

The deceased donation is a strict prohibition in Spain that avoids revealing receivers' or donors' identities. Consequently, it eludes potential psychological ailments without knowing who has been the donor or the recipient of the organ of a loved one who has died, and who has been given access to a transplant.

This principle of confidentiality is rigorous in the case of a living donation.

Presently in Mexico, there is no forbiddance for the receiver to know who was his deceased donor. The basis of the Regulation of the General Law of Health on Transplants determines that the data basis of the National Registry of Transplants will be confidential. In other words, the names of the people looking for a donor cannot be shared except for the ones approved by the legislation.

THE CRIME OF ORGAN TRAFFICKING

In Article 156 of the Penal Code in Spain, organ trafficking and organ trading have been penalized since 2010. Article 177 from this text also typifies what is known as “trafficking for the procurement of human organs”; a hidden degree to use other's people bodies to satisfy a necessity without doubting how to cure one's ill health.

Article 156 punishes the behaviors such as promotion, enhancement, facilitation, or publicity of organ trading.

In Mexico, Articles 11 Bis, Section B, subsection III of the Federal Criminal Code and 461, 462, and 462 Bis of the General Health Law establish that whoever transfers or tries to transfer organs, tissues, or components of living human beings or deceased ones outside national territory without the permission from the Secretary of Health is committing organ trafficking.

Similarly to Spain, in Mexico, the Migration Law is determined in Article 159 that will be punishable by imprisonment to those with the purpose of trafficking transfer one or more people to another country without the correspondent document to make direct or indirect profits.

Based on the beforementioned, it can be called human trafficking. Article 160 of the same Law mentions that imprisonment could increase when the mentioned behavior is done in conditions or with the means that endanger or are likely to endanger health, integrity, security, or life resulting in inhumane or degrading treatment of those involved.

All of the above is similar to the one exposed in Spain. Both countries sentence the illegal obtaining of organs with the purpose of trading. Wondering if any moment we have asked if it is prudent to approve and regulate organ trading correctly.

Many of us have thought that if that possibility existed, there were not many people on the waiting list for a transplant, and it could be a benefit for both “seller” and “buyer”.

The one who could sell his organs would have a moratorium advantage, and the one who buy it would be healthy. Unfortunately, there are disadvantages; if human trafficking is encouraged to obtain and sell organs. Everything would be under the person’s consent that will be willing to sell his organ. All the previously mentioned, it would violate the principles and values of the ethics of no trading.

a) Dignity

All the principles revolve around a principal idea which is human dignity. In that sense, the human being has dignity, and he does not have a price, is always subject to himself, not an object.

The right of organ donation relative to legal status consists of exercising a very personal right to dispose of their own body that involves the following

characteristics: innate, extra-patrimonial, lifelong exercise, relatively unavailable to the holder himself.

a) Informed Consent and Trust

Trust is the foundation on which social relationships are built without a minimum of trust, relationships will not exist. Informed consent planned in the law constitutes an integrative element of trust, which must predominate while doing a transplant and being used as a tool to balance the relationship among procurement teams and transplants and the patients with their families.

In Guideline No. 3, WHO states that "...an organ should be removed from the body of an adult related living donor for transplantation purposes if the donor gives free consent. The donor should be free from undue influences and pressure and be sufficiently informed to understand and weigh the risks, benefits, and consequences of consenting.

The purchase or liberalization of organ donation involves a decrease in altruistic and supportive attitudes. When the human body can be treated as an ordinary property that is sold at known or predetermined prices, it is an invitation of corruption to society, and access to an unfair system and distribution of organs, since the rich will always be in the last place as the receiver, and the poor in the places of donation.

In the Conference of Munich in 1990, it was clearly stated that “It must be forbidden that organ and tissue trading is used to do a transplant...Announcing the necessity or the availability of the organs, to get a payment, which must be banned” (Bioethics Committee INCUCAI, 2008, p. 12).

REFERENCES

Bioethics Committee INCUCAI. (2008). *Ethics and Transplantation A selection of Documents on the 20th anniversary of the Committee* (First). INCUCAI. https://bancos.salud.gob.ar/sites/default/files/2018-10/0000001272cnt-etica_y_trasplante.pdf

MSSI. (s.f.) MSSI performs a kidney cross donation, for the first time at Hospital La Raza | Web site «Acercando el IMSS al Ciudadano». (s. f.). <http://www.imss.gob.mx/prensa/archivo/201712/380>

Muñana-Rodríguez, J. E., & Ramírez-Elías, A.. (2014). Glasgow Coma Scale: origin, analysis, and appropriate use. *University Nursing*, 11(1), 24-35. Retrieved on May 06, 2023, from http://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S1665-70632014000100005&lng=es&tlng=es

Pacheco Gómez, A. (2011). Legitimation of the Biomedical Act. Editorial Alfíl.

Pérez Villares, J.M.. (2015). Donation in asystole. *Cuadernos de Medicina Forense*, 21(1-2), 43-49. <https://dx.doi.org/10.4321/S1135-76062015000100006>

Tenza, E., Valero, R., & Arraez, V. (2017, April 1). Estimation of potential donors in cardiocirculatory death at the Hospital General Universitario de Elche. *Medicina Intensiva*. <https://doi.org/10.1016/j.medin.2016.08.003>

Varelas, P. N., Gronseth, G. S., & Greer, D. M. (2010). Evidence-based guideline update: Determining brain death in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*, 74(23), 1911-1918. <https://doi.org/10.1212/wnl.0b013e3181e242a8>

World Health Organization. (2009). Human organ and tissue transplantation. Report of the Secretariat. Retrieved April 27, 2023, from https://apps.who.int/gb/ebwha/pdf_files/A62/A62_15-sp.pdf