PROCESS OF ORGAN DONATION FOR TRANSPLANTATION: COMPARATIVE ANALYSIS BETWEEN LAWS

PROCESSO DE DOAÇÃO DE ÓRGÃOS PARA TRANSPLANTE: ANÁLISE COMPARATIVA ENTRE LEGISLAÇÕES

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ABSTRACT

Objective: To present a historical report about legislation on the process of organ donation for transplantation in Brazil and in Portugal and to carry out a comparative analysis between both legislations. Method: Bibliography review, considering books, theses, dissertations and documents of the Ministry of Health, dealing with the legislation on organ transplantation in Brazil and Portugal, as well as a literature search in electronic BIREME/BVS databases. Results: Legislative systems in both countries adopt different principles of post-mortem donation. While in Brazil availability of organs is a family choice, in Portugal all citizens are considered as potential donors, unless they have not expressed against donation. Conclusion: Individual decision can favor an increase in the number of donors. Once individuals have expressed their willingness, donation becomes law, while the family’s decision involves grieving, influences of society, religion and opinion of other family members who experience emotional pressures at the moment of losing a family member. However, legislations are elaborated in consonance with the reality of their peoples. Descriptors: nursing; organ transplantation; directed tissue donation; legislation.

RESUMEN

Objetivo: presentar un relato histórico sobre la legislación del proceso de donación de órganos para trasplante en Brasil y en Portugal y a su vez realizar un análisis comparativo entre las dos legislaciones. Método: Revisión bibliográfica, considerando libros, tesis y documentos del Ministerio de Salud, que tratan de la legislación del trasplante de órganos en Brasil y en Portugal, así como una búsqueda bibliográfica en la base de datos electrónica BIREME/BVS. Resultados: Los sistemas legislativos en las dos naciones adoptan diferentes principios de donación post-mortem. En Brasil la disponibilidad de los órganos queda a criterio de la familia, en Portugal todos los ciudadanos son considerados potenciales donantes, a menos que no hayan manifestado su voluntad a la familia. Conclusion: La decisión individualizada puede favorecer un aumento del número de donantes. Una vez que el individuo no manifestó su deseo en vida, la decisión se torna ley, mientras que la decisión de la familia envuelve la situación del luto, influencias de la sociedad, religión y la opinión de otros familiares que sufren las presiones emocionales en el momento de la pérdida de un miembro de la familia. Por ello, la legislación es elaborada en consonancia con su realidad. Descriptores: enfermería; trasplante de órganos; donación dirigida de tejidos; legislación.

INTEGRATIVE LITERATURE REVIEW ARTICLE

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INTRODUCTION

Recent scientific and technological advances allowed the transplantation of organs and tissues of various types in a saving and safely way to patients with various types of illnesses. However, a common problem in all countries is the disproportionate growth of patients on waiting lists in relation to the number of donors. This causes the death of many individuals who are waiting for an organ to save their lives. Several factors cause this disproportionality, among them the refusal of family members to donate organs of patients after brain death, because they are not aware of the procedure or even due to religious beliefs.

Many countries adopt specific legislation relating to this subject, aiming at a better proportionality between the number of donors and waiting lists. Countries such as Austria, Denmark, Sweden, Finland and Germany are part of the Eurotransplant International Foundation, which is responsible for allocating organs in these and some other countries. Despite belonging to the same organization, they differ in the way of consent. In Germany, the consent is informed, while in Austria, it is presumed, as we shall see below concerning Portugal. Other European countries, such as Spain, France and Italy, also adopt the presumed consent, while the entire United Kingdom, Switzerland and the Netherlands prefer the informed consent, which is the regulation followed in Brazil.

In the United States, although they have been looking for some standardization for a certain period of time, some of the 50 states differ on the matter. These states, with a view to accelerating the process of increasing the number of donors and facilitate the donation, created the Uniform Anatomical Gift Act (UAGA) of 1968, 1987 and 2006, the National Organ Transplant Act (NOTA) of 1984, and the Patient Self-Determination Act (PSDA) of 1990.

In Latin America, the legislation contemplates the diagnosis of brain death, the medical criteria for allocation of organs/tissues, the prohibition of marketing and penalties. Regarding consent, in some countries such as Argentina, Colombia, Costa Rica, Dominican Republic, Ecuador, Mexico, Panama, Paraguay and Uruguay, it is presumed and in other countries such as Bolivia, Brazil, Chile, Cuba, El Salvador, Guatemala, Honduras, Nicaragua, Puerto Rico and Venezuela, the consent is informed. However, in all countries, family members are consulted on the donation process.

Brazil has one of the largest public programs of organ and tissue transplantation in the world. The country has more than 500 health care centers and approximately 1,300 medical teams prepared and authorized to perform transplantations. Nevertheless, according to data from the Brazilian Association of Organ Transplantations, 63,866 people were on waiting lists in December 2010. At the end of 2010, Brazil had 9.6 donors per million inhabitants.

Portugal is considered to be the second country in the world of the relative number of donors -after Spain- with 26.7 of them per million inhabitants, which represents a higher number than the Brazilian one. It is considered that the Portuguese State has an advanced legislation on the subject, besides a greater awareness in the population and adequate organization. Two every three Portuguese individuals affirm to be available for donation of organs after death. In this country, the type of consent used is presumed and doctors may remove organs of all adults who die, unless a person has registered in life being a non-donor. Therefore, consent of families is not necessary.

OBJECTIVE

● To present a historical report about legislation on the process of organ donation for transplantation in Brazil and in Portugal and to carry out a comparative analysis between both legislations.

METHOD

It is a study of bibliographic review, which aims to synthesize and summarize in narrative terms material of research literature regarding legislation on donation and transplantation of organs.

The bibliographic sources searched were printed materials such as books, dissertations, theses, documents of the Ministry of Health, dealing with organ transplant legislation in Brazil and in Portugal. In addition, a literature search was carried out in BIREME/BVS electronic database, through the Descriptors in Health Sciences: transplantation of organs, directed tissue donation, and legislation.

The criteria for inclusion in the research were articles, dissertations, theses and full original documents, available online and free of charge. The selected materials were analyzed through exploratory and comparative reading of Portuguese and Brazilian
process, the family assumed responsibility for the destination of the organs.10

In 2001, Law No. 10.211/2001 repealed some provisions of the provisional measures, in addition to modify substantially the Law of 1997. Today, we can say that we have in force the Law No. 9.434/97, amended by provisional measures and by Laws No. 10.211/2001 and 11.521/2007. This law changes the article 4 of the original law and argues that the removal of tissues, organs and body parts from deceased individuals for transplantation or other therapeutic purpose, will depend on the authorization of the spouse or relative, of legal age, obeying the line of succession, straight or collateral, up to the second degree, signed in the document endorsed by two witnesses present to verify the death.11

Thus, this law gives all the power of decision on the destination of the organs of the deceased person to the family, obeying the line of succession. In addition, its article 2 makes invalid any statement in the identity card or the national driver’s license.11

Other important aspects are inter vivos donation. Any individual legally able can dispose of organs or tissues for transplantation to relatives up to the fourth degree or for anyone else, since they have judicial authorization. This provision, regulated by article 9 of the law, serves as a way to restrain the sale of organs, which is prohibited in Brazil. As for individuals legally incapable, they can also donate organs or tissues, provided there is consent of both parents or legal guardians and judicial authorization, prevented that the procedure does not offer health risks (Paragraph 6).11

Health centers that were not authorized to remove organs and tissues were forced by Law No. 11.521/2007 to immediately permit the transfer of the patient or concede their facilities in order to provide support to the medical-surgical team for the removal and transplantation. In addition, they had to disclose information about the benefits of voluntary donation of umbilical cord and placenta blood of newborns.12

There are also some illegal procedures stipulated in the legislation regarding organ transplantation. Article 14 deals with the main among them: Removing organs or tissues not in compliance with the law has a confinement sentence of two to six years, plus a fine. Yet, it has a number of qualifiers, like removing organs from living people and cause life threatening, inability to usual activities, limbs
weakness or childbirth acceleration, which has a confinement sentence of three to ten years, plus a fine, and even worse, if it causes abortion, incurable illness, inability to work, loss or impairment of limbs or permanent deformity, punished will be imprisonment of four to twelve years and a fine and, if it causes death, confinement sentence of eight to twenty years, plus a fine. Marketing of tissues, whether buying or selling, is punished with imprisonment of three to eight years and a fine (Article 15).\(^9\)

For health centers, there are administrative penalties, charged against institutions where crimes established in the Articles 14 to 17 of the Law occur.

♦ Portuguese Legislation

Portugal stands out as one of the nations with best relation between the population and donors in the world. According to authorities as Linhares Furtado, surgeon who performed the first transplant of organs in the country, and Morais Sarmento, chairman of the Portuguese Society of Transplantation, Portugal has a very advanced legislation on the subject.\(^6\)

The current legislation on organs procurement and transplantation in Portugal arose through Law No. 12, April 22\(^\text{nd}\), 1993, which repealed the previous law of 1976. In its Article 2, it highlights that the law does not apply to foreigners occasionally in the country, although it is applied to foreigners residing in Portugal. It is important to emphasize the proscription of marketing of organs and tissues and the total prohibition of non-regenerating organ donation by underage living children, regardless of parental consent.\(^11\)

Regarding this law, it was possible to observe the Lusitanian positioning in favor of the principle of presumed consent, because in its Article 10, the law claims that all residents in Portugal should be considered as potential donors, including foreigners and stateless individuals. Those who did not wish to be donors of organs and tissues must express their decision at the Ministry of Health, this way being appended to RENNDA (National Register of Non-Donors), in addition to receiving a non-donor card.\(^13\)

Information about the formalities of the law is set out in Article 13 and the additional provisions, which deal with matters such as information campaigns, in Article 15.\(^14\) In the criminal sphere, in Article 16, it only states that violators will be civil, criminal or disciplinary liable in case they commit any infraction.\(^14\)

After fourteen years, this original legislation was amended by Law No. 22/2007. In addition to make some simple changes in the drafting, Article 1A stated the exact definition to the jurisdiction of each expression meaning: organ, tissue, cell, donor, donation and procurement. As novelty, it also has the tracking of organs and tissues in Article 4.\(^14\)

Another significant change is that there is now a better provision of donation by underage individuals, although non-regenerating organ donation - as kidneys for example- is prohibited. The amendment states that the situation must meet various requirements, such as the lack of compatible donor, the receiver shall be brother or sister of the donor, and donation must be necessary for the preservation of the life of the receiver.\(^14\)

The Entity for the Admissibility of Procurement for Transplantation is also created and it is responsible for the opinion regarding live donation of organs, as in the new case of non-regenerating organ donors that are not residents in Portugal.\(^15\)

Earlier than expected, but always striving to evolve, the legislation was modified again by Law No. 12/2009. Nevertheless, it did not make substantial changes in its purpose.\(^16\)

In 2010, the European Parliament approved a directive aimed at facilitating the donation and transplantation of organs in the European Union countries. It establishes common quality and safety standards for the procurement, transport and use of organs, as well as establishing a minimum set of data to be collected at each donation. Countries will have two years to incorporate these guidelines into their internal legislation.\(^17\)

♦ Comparative analysis between the Portuguese and Brazilian legislations concerning organ transplantation

Legal systems in both nations adopted different principles. While in Brazil the disposal of organs is currently at the discretion of the family, in Portugal the principle of presumed consent is adopted, because, according to Article 10 of Portuguese legislation, all nationals, stateless or foreigner individuals residing in the country are considered potential donors, provided that they have not expressed their desire of being non-donors at the Ministry of Health.\(^18\)

In 1997, in the original text of the Brazilian Transplant Law, the principle of presumed
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As previously mentioned, Portuguese law is comparatively also more complete as it specifically defines the main expressions used in the process. Brazilian lawmakers did not see such a need. On the contrary, through several articles and situations, the Brazilian legislation regulates in detail criminal liability, regarding the most known types of donations that can occur in this process, in addition to the penalties corresponding to each one of them. On the other hand, the Lusitanian preferred to draw up only one article with a broad regulation that only specifies civil and criminal responsibilities in violation of law.

Another divergent aspect is that in Portugal, the removal of non-regenerating organs from living underage donors is prohibited and, even if regenerating, it must obey to a cumulative series of requirements. In the Brazilian legislation, this procedure depends on approval from both parents and is only permitted in the case of bone marrow transplantation.

In Portugal, even today, it is possible to say that the consent of the family is disregarded in the process, while in Brazil it is the main figure. This is one of the criticisms made against the Portuguese system.

The provision about cases of nationality is another factor that stands out in the Portuguese system, whereas it is not observed in the Brazilian system. In Portugal, it is established that foreigners and stateless individuals residing in the country are potential donors, and there is a specific provision for foreigners who are occasionally in the country. Brazilian legislation is omissive in this regard and there is no manifestation in this respect.

FINAL CONSIDERATIONS

The reviewed countries have different legislations regarding organ donation and transplantation and such differences seem to influence the number of donors. Among the legal differences found, it stands out that the family consent is decisive in Brazil, while in Portugal, donation is an individual decision, which originates from each individual’s willingness, regardless of parental issues.

It is believed that an individualized decision can favor an increase in the number of donors. Once individuals have expressed their willingness while living, this willingness becomes law. On the other hand, family decision involves mourning and the influences of society, religion and the opinion of other family members who experience emotional
pressures at the moment of losing a family member. However, different legislations are drafted in consonance with the reality of their people. Therefore, it is important to analyze the acceptance that legislations will have on the territories to be applied. Any change should be deeply analyzed considering the sociological and cultural aspects of the population on which the legislation will be in force.

The Brazilian laws and public programs need to hasten the donation process and encourage the growth of the number of donors in order to have positive reflexes on reducing the number of individuals in transplant waiting lists. It is also essential that the structure and organization of medical institutions and medical/surgical teams favor this growth. The structural and trained human resources deficiencies for procurement and transplantation of organs are undoubtedly one of the reasons that reduce considerably the organ donation statistics in Brazil.

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