

# Organ donation and human tissues: transplantation in Spain and Brazil

Gustavo Henrique de Freitas Coelho<sup>1</sup>, Alcino Eduardo Bonella<sup>2</sup>

## Abstract

This essay, based on data referring to Brazil and Spain, addresses aspects relevant to the scenario of organ donation and transplantation, such as the relationship between supply and demand, current legislation, costs, and possible improvements to increase donation rates and performance in the transplantation process as a whole. The objective is to present current empirical data that increase the relevant empirical knowledge for the bioethical evaluation in an organized way. The two countries stand out when it comes to transplants, Brazil, because it has the largest public system of organ transplants in the world; Spain, for decades the highest rate of effective donor per million inhabitants. Our initial data analyses suggest the need to deal more explicitly with the interests of those affected and with the public opinion, within a systemic articulation between legislation, evidence-based public policies, and research.

**Keywords:** Bioethics. Transplantation. Tissue and organ procurement-Gift Giving. Statistics. Legislation.

## Resumo

### Doação de órgãos e tecidos humanos: a transplantação na Espanha e no Brasil

A partir de dados brasileiros e espanhóis, este artigo aborda aspectos relevantes da doação e transplantes de órgãos, como a relação entre oferta e demanda, legislação vigente, custos e possíveis estratégias para aumentar taxas de doação e melhorar de forma geral o processo de transplantes. O objetivo deste artigo é apresentar dados empíricos atuais que incrementem o conhecimento relevante para a avaliação bioética. Os dois países se destacam: o Brasil por ter o maior sistema público de transplantes de órgãos do mundo, e a Espanha por manter há décadas o maior índice de doadores efetivos por milhão de pessoas. Análise inicial dos dados sugere a necessidade de lidar mais abertamente com os interesses dos afetados e a opinião pública, criando articulação sistêmica entre legislação, políticas públicas baseadas em evidências e pesquisa.

**Palavras-chave:** Bioética. Transplante. Obtenção de tecidos e órgãos-Doações. Estatística. Legislação.

## Resumen

### Donación de órganos y tejidos humanos: el trasplante en España y en Brasil

A partir de datos brasileños y españoles, este artículo aborda aspectos relevantes de la donación y el trasplante de órganos, como la relación entre oferta y demanda, la legislación vigente, los costos y las posibles estrategias para aumentar las tasas de donación y mejorar de forma general el proceso de trasplante. El objetivo de este artículo es presentar datos empíricos actuales que incrementen el conocimiento relevante para la evaluación bioética. Los dos países se destacan: Brasil, por poseer el mayor sistema público de trasplante de órganos del mundo; España, por mantener desde hace décadas el mayor índice de donadores efectivos por cada millón de personas. Un análisis inicial de los datos sugiere la necesidad de lidiar más abiertamente con los intereses de los afectados y con la opinión pública, creando una articulación sistémica entre legislación, políticas públicas basadas en evidencias e investigación.

**Palabras clave:** Bioética. Trasplante. Obtención de tejidos y órganos-Donaciones. Estadística. Legislación.

1. **Graduado** gusege@hotmail.com – Universidade Federal de Uberlândia (UFU) 2. **Doutor** abonella@gmail.com – UFU, Uberlândia/MG, Brasil.

## Correspondência

Gustavo Henrique de Freitas Coelho – Rua Aguapé, 371, casa 6, Chácaras Tubalina CEP 38413-288. Uberlândia/MG, Brasil.

Declararam não haver conflito de interesse.

In 1933 the first transplant was performed in the world, and in 1964 this type of procedure was inaugurated in Brazil with a kidney transplant performed at the Public Servants Hospital of Rio de Janeiro State<sup>1</sup>. Since then, transplantation techniques and immunosuppressive drugs have evolved greatly, so that, besides enjoying a better quality of life, the transplanted patient also survives longer compared to life expectancy without the procedure.

However, the demand for transplant organs is increasing continuously, and the relationship between the number of patients on the waiting list and the organs available is increasingly disproportionate. Because of this shortage, organ acceptance criteria are being expanded<sup>2</sup>.

There are currently few absolute contraindications to donation: malignant tumors, except basal cell carcinomas, cervical in situ carcinoma and primitive central nervous system tumors, positive serology for human immunodeficiency virus (HIV) or human T-lymphotropic virus (HTLV) I and II, active and uncontrolled sepsis and active tuberculosis<sup>3</sup>. Conversely, transplantation is indicated for several clinical problems<sup>4</sup>.

The objective of this paper is to structure current empirical data that increase the relevant knowledge for bioethical evaluation. Bioethical values and principles, such as patient autonomy and public beneficence, focus first on the facts they intend to evaluate, and then on possible protocols of conduct. Both the facts of the case and the expectations related to the prescriptions depend on correct empirical knowledge for the bioethical evaluation to be rational and responsible.

Thus, based on data from Brazil and Spain, this article addresses ethically and empirically important aspects of the donation and transplant scenario, such as the relationship between the supply and the demand, current legislation, costs, and possible strategies to increase donation rates and improve the process as well. One all. The chosen countries stand out for two reasons: Brazil has the largest public organ transplant system in the world, and for some decades Spain has been leading the effective donor rate per million people, a *prima facie* example to be considered seriously.

### Transplants in numbers: world data

In 2015, the world average donation rate per million population (PMP) was 16.96, with 126,760

transplants performed in total, of which 84,437 were kidney, 27,759 liver, 7,023 heart, 5,046 lung, 2,299 of pancreas and 196 small intestine transplants<sup>5</sup>. In 2014, 119,873 organs were transplanted (79,948 kidneys, 26,151 livers, 6,542 hearts, 4,689 lungs, 2,328 pancreas and 215 small intestines). These numbers account for less than 10% of the world's need for organs<sup>6</sup>.

According to data from 2004, it is estimated that around 3% of the budget of the EU Member States for health is directed to patients awaiting this procedure. Ten thousand kidney transplant patients would save healthcare more than € 200 million per year when compared to transplant and dialysis costs (not including structural expenses)<sup>7</sup>.

Different reasons explain the scarcity of organs. Most donors are individuals who died in hospital after severe brain damage, diagnosed with brain death. However, only 1% of the dead and less than 3% of the hospital deceased are in this situation, i.e. the number of potential donors is very low<sup>7</sup>.

In addition, the process of organ donation and procurement is a delicate one as it should be done within a few hours, as there is a time limit between donor organ removal and its implantation into the recipient, the so-called "ischemia time". Normally accepted maximum periods are six hours for heart and lung, 24 hours for liver and pancreas, 48 hours for kidneys, seven days for corneas and up to five years for bones<sup>4</sup>.

On the other hand, a report from the World Health Organization (WHO)<sup>8</sup> points out that in 2015 there were 1.1 billion smokers in the world, 42 million overweight children younger than 5 y.o., 1.8 billion people consuming contaminated water, and 946 million living with open sewage. These data suggest that the growing demand for transplant organs may have among its causes mitigable or preventable factors such as adequate diet, decreased physical inactivity, reduced tobacco and alcohol consumption and promotion of basic health actions such as water and sewage treatment.

These indices suggest that, first of all, the difficulty with transplantation should be addressed with social and health public policies that reduce health problems directly linked to diseases that maintain or increase the transplantation queue. This is because by combating causes or risk factors for disease and health conditions, the problem that causes patients in need of organs is attacked. But that still does not solve the short-term problem of obtaining and distributing organs and structuring good protocols in ethical and effective systems.

## Spain, world leader in organ donors

Since 1992, Spain has maintained the world record for PMP organ donors. In 2017, the rate was 46.9 PMP, totaling 2,183 donations and 5,261 transplanted organs, an average of six donations and 14 daily transplants<sup>9</sup>. In the previous year, in 2016, this indicator reached 43.4 PMP, with 2,018 donations and 4,818 transplanted organs<sup>10</sup>. In 2017, 3,269 kidney transplants, 1,247 liver transplants, 304 heart transplants, 363 lung transplants, 70 pancreatic and eight intestinal transplants were performed. For the third consecutive year, they exceeded 100 PMP transplants, reaching in 2017, 113 PMP, reducing the waiting list from 5,480 patients at the end of 2016 to 4,896 at the end of 2017<sup>9</sup>.

By comparison, while in 2017 Spain had 46.9 PMP donors, the European Union recorded 21.5 PMP; the United States, 30.8 PMP; France, 28.7 PMP; Italy, 24.7 PMP; the United Kingdom, 21.6 PMP; and Canada, 19.0 PMP<sup>9</sup>. In Brazil, the average was 16.6 PMP<sup>11</sup>. If we go back to 2015, the rate of deceased organ donors per million inhabitants was 40.2 in Spain, 28.2 in the United States, 28.1 in France and 10.9 in Germany. Also in 2015, Spain reached the rate of 100.7 transplanted patients per million people, well above the European average of 62.4 PMP and higher than the United States, with 92.7 PMP. With only 0.6% of the world's population, 17.6% of all organ donations from the European Union and 6.7% of all donations in the world were made in Spain<sup>12</sup>.

Under Spanish law, every deceased person is presumably an organ donor unless they have expressed a contrary opinion in life. Still, in practice, family members are systematically consulted, with their opinion respected. In 2017, of the 2,509 family interviews conducted in Spain regarding the deceased, family consent was recorded in 2,183 cases (87.1%), while only 326 (12.9%) families refused<sup>13</sup>.

Considering that various organs can be extracted and used from each donor, each family refusal is an opportunity missed simultaneously by several people. As an example, in 2016, in the United States, an average of 3.54 organs were recovered per donor<sup>14</sup>.

## The Spanish transplant model

Spain is considered an example to the world, such is the success of its donation and

transplantation model. In 1989 the Organización Nacional de Trasplantes – National Organization for Transplants (ONT) was created and in 1992, just three years later, the country became the world leader in this type of surgery, with the highest donation rate, since it maintains since. Before the creation of the ONT, organ donation rate in the country did not reach 15 PMP, while family refusal exceeded 27%<sup>9</sup>. From then on, various measures were put in place, including legal adjustments and technical, economic constraints, politicians and physicians:

*The Spanish model is based on the coordination of transplants at three levels: national, autonomous and hospital. The first two levels are funded by the national health administration and maintain an interface with the political, administrative and professional levels. The hospital-level refers to intra-hospital coordination – in which Brazil is also structured concerning organ donation: a physician acts as coordinator and a team of trained people from the hospital itself performs organ procurement activities (detection potential donors, family interviews, family support, etc.). In this model, there is a reimbursement for activities related to organ procurement performed at the hospital, and an effective method of brain death protocol (BD) audits ensures the quality of the process. The Spanish model also has a media education and outreach system and an open telephone channel where information about the donation and transplantation process is available to the general public<sup>15</sup>.*

The entire process is funded by ONT, and meetings are held annually with journalists to announce and publicize campaigns. Besides, annual courses are also held for legal and forensic professionals, because there are donations that require judicial authorization, such as in cases of head injuries due to traffic accidents, violent deaths, or sudden deaths that need to be ruled out. violent. The goal is to bring them closer to the legislative and technical news and inform that in most cases there is no problem or interference with the legal process if the deceased is a donor. And, especially, there is a permanent training activity for everyone involved in the process. We work with scientific societies and take training courses with urgency, emergency, and intensive care professionals. The Critical Situation Communication Course, or the Bad News Communication Course, is aimed specifically at transplant coordinators for the family donation interview<sup>16</sup>.

Among the factors that contributed to the success of the Spanish model were the central role attributed to the transplant coordinator and the concern with training to communicate “bad news” and to convince the family of the importance of authorizing the donation. Since its inception, ONT has trained more than 18,000 coordinators. According to the Spanish Ministerio de Sanidad, Servicios Sociales e Igualdad (Ministry of Health, Social Services and Equality):

*The key to this success lies in a model of people and resource management, purely Spanish, known throughout the world as a Spanish transplant model, based on an extensive network of hospital coordinators, perfectly formed to detect donor positions and interns to work with their families; a public health system with professionals of the highest level, and the generosity of the citizens, which responds magnificently when they have clear goals. These elements, together with model legislation and the enormous sensitivity of the means of communication before the donation and transplantation process, have converted to Spain in an international referent and an example to follow for all those countries that want to improve their donation systems and transplants<sup>17</sup>.*

Therefore, it is evident that it is not possible to attribute the success of the “spanish transplant model” and the growth of the PMP donation rate to one strategy, but the overall structuring of the health system. With the ONT, Spain recognizes its world-leading role in transplantation and advises countries on five continents. It has collaborated with WHO since 2006, leading the transplant process worldwide, combating organ trafficking and transplant tourism, and since 2008 manages the World Transplant Registry<sup>9</sup>.

In 2005, in an attempt to disseminate the Spanish transplant model and train coordinators, ONT created the Ibero-American Donor and Transplant Council Network, which includes Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Spain, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Portugal, Dominican Republic, Uruguay, and Venezuela. In 2017, the 13th edition of the Master Alianza en Donación de Trasplantes, Tejidos y Células, an ONT program that seeks to train professionals from Latin American countries in Spanish centers and specialized courses, was attended by 26 students from 12 countries. By

the end of the meeting, the Master Alianza had already trained 412 students from all the countries that make up the community, of which 53 were Brazilians<sup>18</sup>. With the implementation of this training project, the number of donations in the Ibero-American region increased by 60%<sup>12</sup>.

In addition to the courses to train transplant center coordinators, there is also the technical cooperation agreement signed between Spain and Brazil in 2014. The document foresees the formation of teams of surgeons in new or little-explored fields in our country, such as the withdrawal of donor organs with cardiac death or multiple organ transplantation<sup>19</sup>. In 2017, in Spain, donations in asystole (cardiac death) accounted for 26% of this entire area, representing the most promising pathway for transplant expansion<sup>9</sup>.

### Organ transplants in Brazil

In this study, the report “Dimensionamento dos transplantes no Brasil e em cada estado” (2010-2017) (Transplant Dimensioning in Brazil and in each state), presented by the Associação Brasileira de Transplante de Órgãos – Brazilian Association of Organ Transplantation (ABTO)<sup>11</sup>, was the primary source for obtaining Brazilian statistical data. According to the report, in 2017 the country had 3,415 effective donors, up 14% over the previous year (2,981 donors), reaching a rate of 16.6 PMP (well below the Spanish figure, which reached 46.9 PMP in 2007).

Although this indicator corresponds to the national average, regional data vary significantly. The Southern region has much higher levels, with an effective donor index of 34.1 PMP, followed by the Southeast (17.9 PMP), Midwest (11.7 PMP), Northeast (10.8 PMP) and North (3.9 PMP).

With 206 million inhabitants in 2017, Brazil performed 8,642 transplants, of which 380 were heart, 2,109 liver, 112 pancreas, 112 lung, and 5,929 kidney. Add to this total another 15,242 corneal transplants. By the end of that year, 32,402 patients were in the waiting list for organs: 21,059 for a kidney, 1,101 for a liver, 255 for a heart, 180 for lungs, 511 for pancreas and kidney, and 9,266 for a cornea. Moreover, there were another 1,039 active pediatric patients on the waiting list.

During 2017, 10,565 people joined the waiting list, while 1,180 patients, 4 of them pediatric, died while waiting for an organ. Although cornea, kidney,

liver, heart, and lung, together account for 23,772 transplants performed that year, the estimated need was 39,362 organs, representing a deficit of 15,590 organs in 2017 alone.

In comparison, the United States, with a population of 325 million, carried out 34,770 transplants from 16,473 donors in the same year. At the end of 2017, 115 thousand patients were waiting for an organ. Currently, 20 people die every day waiting for a transplant, while every 10 minutes another person is added to the waiting list<sup>20</sup>.

In Brazil, more than 90% of transplants are funded by the Sistema Único de Saúde – Unified Health System (SUS). In 2017, this rate was 98% for kidney and pancreas transplants, 96% for heart and kidney, 95% for liver, 93% for lung and 90% for pancreas transplants. Since 2008, the budget for this type of surgery has more than doubled, from R\$ 453.3 million to R\$ 942.2 million in 2016, considering only the expenses with outpatient (exam) and hospital procedures (transplants). Brazil has the largest public transplantation system in the world and patients can benefit from free medication after the procedure. Considering investments in immunosuppressants, the budget for 2016 was over R\$ 1.356 billion<sup>21</sup>. In 2017, public spending on transplantation, excluding immunosuppressants, totaled just over 1 billion<sup>22</sup>.

### Legislation, presumed consent and family refusal in Brazil

Organ transplants in Brazil began in the 1960s – with kidney transplants in 1964 and 1965, followed by the first heart transplant in 1968<sup>1</sup>. However, this surgery was not regulated until 1997, with Law 9,434<sup>23</sup>, which deals with the provision of *post mortem* of organs, tissues, and parts of the human body for transplantation purposes; criteria for living donor transplantation; and criminal and administrative sanctions for non-compliance. It was regulated by Decree 2.268/1997<sup>24</sup>, which created the Sistema Nacional de Transplantes – SNT (National Transplant System) and its branches, such as state agencies and Centrais de Notificação, Captação e Distribuição de Órgãos e Tecidos – Centers for Organs and Tissue Notification, Collection and Distribution (CNDCO). Subsequently, Decree 9.175/2017, which also regulated the Transplant Law, dealt with *the disposition of organs, tissues, cells, and parts of the human body for transplantation and treatment purposes*<sup>25</sup>.

Law 9,434/1997<sup>23</sup> changed the type of donation valid in the country, which until then was consented, that is, it was necessary to manifest in life for or against the donation in case of death. With the Transplant Law, authorization was assumed, and the dissenting should formally express their position. This registration, for or against organ donation, was made on the identity card or national driver's license. However, Law 10,211/2001<sup>26</sup> extinguished the presumed donation and provided written authorization of first or second degree relatives or spouse with a proven relationship, without which organ removal would be prevented, regardless of the potential donor's wish in life. Records previously held in identification documents are no longer valid<sup>4</sup>.

In the opposite direction, with 5,746 transplants performed in 2015 and after the deaths of 553 of the 21,000 patients waiting on the waiting list, France enacted its Health Act. The determination established that, as of January 1, 2017, people who objected to the presumed consent should formally express this and enter their refusal in the national register, over the Internet or in a signed document delivered to a relative. Mere oral refusal by family members is no longer accepted in the country. In 2015, when the standard was drafted, the French had a family refusal rate of 32.5%<sup>27</sup>. The Netherlands also legally established that from 2020 onwards all citizens over the age of 18, after being consulted and not expressing an opposing interest are registered as potential organ donors<sup>28</sup>. Similar legislation already exists in Belgium and Portugal.

In Brazil, the family refusal rate reached almost 50% in 2013, and since then it has been gradually decreasing in percentage terms, although it remains practically stable in relation to total refusals. In the year in question there were 2,622 cases of family refusal (47%), 2,610 cases in 2014 (46%), 2,613 cases in 2015 (44%) and 2,571 cases in 2016 (43%). Notifications of potential donors reached 51.6 PMP in 2017, with 10,629 reported cases, while the refusal of family members in interviews reached 42% with 2,740 cases. Of all federative units in Brazil, in 13 states the refusal rate exceeded 50%, reaching 80% in Mato Grosso and 74% in Sergipe<sup>11</sup>.

To fulfill the gap left by Law 10,211/2001, Senate Bill (PLS) 453/2017 was presented, which proposes to change art. 4 of Law No. 9,434 of February 4, 1997, to *make it explicit that family consent, in the case of donation of organs, tissues and parts of the human body after death, is only*

necessary when the potential donor has expressly and validly expressed its views in life<sup>29</sup>. The bill proposes a balance between the presumed donation legislation and the current one, which delegates veto power to the family.

Still regarding the high rate of this refusal, the president of ABTO states that *the great obstacle is the lack of knowledge to know that brain death is a situation of absolute irreversibility*<sup>30</sup>. According to the deputy coordinator of the Organ Procurement Organization of the São Paulo Clinical Hospital, *more than patient families, many health professionals do not understand or accept a diagnosis of brain death*<sup>30</sup>.

### **Brain death and the wait for organs in Brazil**

The criteria for the diagnosis of brain death were established in Brazil by the Resolution of the Conselho Federal de Medicina – Federal Council of Medicine (CFM) 1,480/1997. This resolution was effective for 20 years, during which time more than 100,000 diagnoses occurred in the country<sup>31</sup>. CFM Resolution 2,173/2017<sup>32</sup> updated these criteria and replaced CFM Resolution 1,480/1997, in compliance with Law 9,434/1997 and Decree 9,175/2017.

According to Resolution CFM 2,173/2017, brain death (BD) is characterized by the *complete and irreversible loss of brain functions, defined by the cessation of cortical and brain stem activities (...). It is established by the definitive and irreversible loss of brain functions due to a known, proven and capable cause for the clinical condition. The diagnosis of BD is absolutely certain. The determination of BD should be performed in a standardized manner, with 100% specificity (no false diagnosis of BD). Any doubt in determining BD precludes this diagnosis. Procedures for BD determination should be performed in all patients in nonperceptive coma and apnea, regardless of organ and tissue donor status*<sup>32</sup>.

Among the changes introduced by the new resolution is the possibility for other specialists, besides the neurologist, to diagnose brain death. The 1997 determination stated that the diagnosis should be made by two physicians, one of whom must be a neurologist. The 2017 Resolution, on the other hand, requires one of the physicians to specialize in one of the following areas: intensive care, pediatric intensive care, neurology, pediatric neurology, neurosurgery or emergency medicine. The second physician must have at least one year of experience in the care of comatose patients and

have followed or determined at least ten brain death determinations or have attended a training course for this.

In addition to the clinical examination performed by two physicians, the patient should undergo apnea testing and complementary examinations to certify that the brain has no electrical activity (electroencephalogram) or blood circulation (CT angiography, angiography, brain resonance, and scintigraphy). After careful clinical and laboratory evaluation, the brain-dead patient is considered a potential organ donor. From this, possible contraindications that pose risks to the recipients are verified. The family should be notified of the patient's death, and then an appropriate professional should conduct the interview for consent for organ and tissue donation. Throughout the process, the potential donor needs to be maintained in stable conditions so as not to derail the donation or compromise the quality of the organs and tissues<sup>3</sup>.

Once the patient meets the clinical criteria for brain death established in Resolution CFM 2,173/2017, article 13 of Law 9,434/1997 states that *it is mandatory for all health facilities to notify the organ reporting, collection and distribution centers of the federal unit where it occurs, of the diagnosis of brain death made in patients treated by them*<sup>23</sup>. And the sole paragraph of the same article adds: *after the notification provided for in the caput of this article, health facilities not authorized to remove tissues, organs or parts of the human body intended for transplantation or treatment should allow the immediate removal of the patient or make its facilities available and provide the necessary operational support to the medical and surgical removal and transplantation teams, in which case they will be reimbursed in accordance with law*<sup>23</sup>. This recommendation is reinforced by Decree 9,175/2017<sup>25</sup>.

In June 2018 there were 32,716 patients waiting for transplants in Brazil<sup>33</sup>. To ensure the democratic access that guarantees citizens the same opportunities, *each organization has a specific waiting list, based on Law No. 9,434/1997, Decree No. 2,268/1997 and in Ordinance GM/MS 2,600/2009. Patient relationships are managed by the General Coordination of (...) SNT, Ministry of Health, through a computerized system. The main feature of the lists is that they do not work in order of arrival, in which the first to sign up will receive the organ before the second and so on consecutively.*

*Instead, the criteria obey medical conditions. There are three determining factors: blood group compatibility, waiting time and disease severity*<sup>34</sup>.

Ordinance 2,600/2009<sup>35</sup> changed the way of distributing deceased donor organs and changed the single list, which was renamed the Cadastro Técnico Único – Unique Technical Registry (CTU). The patient waiting for transplantation must be enrolled in the CTU, and although the transplantation system is national, distributions are regional. *The CTU is composed of separate organ and tissue lists for each state, with predefined criteria for prioritizing critically ill or dying patients*<sup>36</sup>.

For logistical reasons and to reduce time in ischemia, the system first looks for recipients located in the same state as the donor. If there is no correspondence between priority cases, the organ is made available to the nearest geographically patient who meets the required medical criteria. The SNT allows the queued patient or guardian to access their electronic medical record via the Internet – where they can track organ offers – with the number and password provided at the time of CTU enrollment<sup>35</sup>.

### Transplantation and bioethics: initial discussion

The European Group for Coordination of National Research Programs on Organ Donation and Transplantation highlights that communication is an area where countries generally have less developed initiatives or programs. There are no strategies to train or inform professionals. There are advertising campaigns, but no interactive actions, such as seminars or meetings, targeting specific groups (adolescents, students, health workers, legislators, etc) and new technologies are not used to disseminate them. Also, media relations are not based on a regular or professional communication strategy<sup>7</sup>.

These aspects are already, as can be seen from this work, mitigated or at least confronted in the Spanish system, although everywhere, given the new media interactions and increasing cultural and political complexity, constant reflection and monitoring are probably necessary to maintain and renew the system. However, for initial analysis, the Brazilian reality will be approached.

In Brazil, two major reviews of the SNT have recently been conducted. In 2006, the Tribunal de Contas da União – Federal Court of Accounts (TCU)

presented the “Relatório de avaliação de programa: Programa doação, captação e transplante de órgãos e tecidos”<sup>37</sup> (“Program Evaluation Report: Organ and Tissue Donation, Capture and Transplantation Program”). In 2014, the NGO AmarBrasil presented the “Projeto Pulsar Vida: doação de órgãos e transplantes no Brasil: diagnóstico e diretrizes públicas”<sup>38</sup> (“Pulsing Life Project: Organ Donation and Transplants in Brazil: Diagnosis and Public Guidelines”), reviewing the 2006 report prepared by TCU and proposing correction of “critical nodes” still present in the SNT. According to the TCU, Brazil, *because it hosts the largest public transplantation program, faces a unique opportunity to develop effective mechanisms for monitoring transplant outcomes and may make a significant contribution to improving the science applied to this medical field*<sup>39</sup>.

Almost ten years after the regulation of Law 9,434/1997, the TCU found that the system still does not operate fully, with planning, management, control, and evaluation failures. These aspects have repercussions throughout the SNT, affecting organ uptake and use when they cannot be used where they were obtained<sup>40</sup>. It was also concluded that

*Difficulties in performing pre-transplant examinations by SUS and the suspension of some public transplantation services lead to difficulties in accessing these treatments, especially for the low-income population, distant from transplant centers and without resources to cover travel expenses and particular procedures. It is observed that patients who undergo transplant exams by paying for or through a health plan are able to enroll more quickly on the waiting lists and therefore benefit from the time since list enrollment is a criterion considered in the distribution of several organs*<sup>41</sup>.

In 2014, the diagnosis made by the AmarBrasil project indicated that there were still many of the irregularities pointed out by the TCU in 2006. The report highlights the low rate of notifications of brain death in relation to the universe of potential donors, despite its legal obligation since 1992. Also, it highlights the insecurity of those responsible for diagnosing brain death, the lack of training of those responsible for interviewing family members, poor operational performance of units already qualified to capture organs and tissues, the obsolete communication system and the lack of ground transportation. and air to this end<sup>38</sup>.

About this last aspect, about 30% of the organs for transplantation in the country are sent by plane and, in 2015, 3,800 commercial flights were used for this purpose<sup>42</sup>. Only in June 2016, with the approval of Decree 8,783<sup>43</sup>, a Brazilian Air Force aircraft began to fulfill exclusively the requirements of the Ministry of Health.

Despite the large absolute number of transplants in Brazil, effective performance is still low. In 2017, 10,629 potential donors were notified, but only 3,415 procedures were completed. Family refusal, as already mentioned, is the biggest reason for donor loss. Among other causes, in addition to the 1,232 cases of donor heart failure and 1,683 losses attributed to other reasons, usually related to logistical or operational problems, there were 1,559 donations not performed due to medical contraindications<sup>41</sup>.

In order to increase the number of donations made effective, another fundamental point concerns medical refusal. In this sense, *the intensivist must understand that he should not briefly and impulsively contraindicate cases that do not represent absolute contraindications. For example, there are no age limits for donating most organs, just as donors with positive hepatitis B or hepatitis C serology can be organ donors for carriers of these viruses. Also, although it is not yet the Brazilian reality (there is no technical regulation for this), there are reports of organ donation from HIV carriers to equally carriers. In this sense, we understand that knowledge generates safety and avoids contraindications that may discard organs in good condition*<sup>44</sup>.

According to the AmarBrasil study, the high failure rate is also caused by organ quality, which can be affected by several factors: inaccurate clinical evaluation of the potential donor; improper body maintenance; technical problems and delayed organ removal; packing conditions; and the long time in cold ischemia, which can also be caused by lack of proper and efficient displacement<sup>38</sup>.

Looking at the scenario of the last decades and at what is happening in Europe, to increase the number of donors, and especially to better deal with the issue of family refusal, it is necessary to develop more social marketing strategies to attribute more social value to the donation. In addition, it is necessary to clarify the public as to the irreversibility of the brain death state and to update the existing legislation towards the presumed, consented or combined donation.

However, pilot studies should be conducted on the cost and effectiveness of varied and comparative strategies to increase organ availability to monitor the effects of these policies.

Two ethical aspects draw attention. First, the need to explicitly publicize and reconcile the interests of those in need of organs (and potential donors) with the opinion of society at large and, in particular, with the families of donors. The second point concerns the systemic articulation between legislation, publicity, training, and protocol organization, as well as adequate funding to make donor and transplant growth faster and more consistent. It is not enough just to sensitize the population, it is also necessary to have trained health professionals to efficiently coordinate the donation process, in its operational and human aspects. Even though the population is predisposed to organ donation, the country needs a transplant system that effectively works, otherwise, the donation will not materialize.

Concern about social vulnerability partly justifies legislative restrictions such as existing Brazilian law, according to which family members still have the prerogative to determine, after the death of the loved one, whether or not their organs will be donated, even if the subject authorized it in life. Even so, the vulnerability of patients in waiting and urgency to obtain organs suggests that the legislation be revised, returning to patient autonomy and voluntary consent. It is a constitutional and legal normative principle<sup>45</sup>, as well as an ethical and social value that deserves due recognition.

## Final considerations

Techniques related to transplantation and development of immunosuppressants have evolved considerably worldwide, so that the patient receiving the organ, besides having a better quality of life, also survives longer. Not only does transplantation save lives, but it is also cost-effective when compared to palliative treatments and care. However, following the success of this type of procedure, the demand for transplant organs increases faster than the number of donors available; The number of patients on waiting lists grows disproportionately compared to the number of transplants performed.

The issue does not seem to be consolidated in Brazilian law, and the country lacks social awareness

about the importance of donation. The mechanisms and norms for organ procurement and infrastructure development, both physical and human, capable of supporting this high demand, are still in slow progress, far from exhausting operational and supply potential. However, it must also be considered that family acceptance varies greatly in the regions of Brazil.

Spain has a much higher donor rate than any other country in the world but still needs to develop strategies to lower refusal rates. Brazil, for its part, is already an example of having organized the largest public transplantation system in the world, even though it has problems and challenges to overcome – from high rates of family refusal and organ disposal to logistical and operational problems.

Organ shortage is a challenge facing all countries: current donations can supply less than 10% of organ shortage worldwide. Most donors are patients who died in hospital after severe brain damage and can be diagnosed with brain death. However, the number of potential donors is very low, as no more than 1% of people killed and less than 3% of people who die in the hospital reach this condition<sup>6,7</sup>.

Therefore, these potential donors should be given the highest priority as a means of reducing the gap between organ demand and supply. In this sense, it is noted that the refusal of family members is the main obstacle to be overcome by organ donation programs.

## Referências

- Garcia CD, Pereira JD, Garcia VD, organizadores. Doação e transplante de órgãos e tecidos [Internet]. São Paulo: Segmento Farma; 2015 [acesso 10 jan 2019]. Disponível: <https://bit.ly/2KXGjlc>
- Westphal GA, Garcia VD, Souza RL, Franke CA, Vieira KD, Birkholz VRZ *et al.* Diretrizes para avaliação e validação do potencial doador de órgãos em morte encefálica. Rev Bras Ter Intensiva [Internet]. 2016 [acesso 28 jul 2018];28(3):220-55. Disponível: <https://bit.ly/2XeYMXt>
- Pereira WA, coordenador. Diretrizes básicas para captação e retirada de múltiplos órgãos e tecidos da Associação Brasileira de Transplante de Órgãos [Internet]. São Paulo: ABTO; 2009 [acesso 28 jul 2018]. Disponível: <https://bit.ly/2CMj3rJ>
- Associação Brasileira de Transplante de Órgãos. Entenda a doação de órgãos [Internet]. São Paulo: ABTO; 2002 [acesso 28 jul 2018]. Disponível: <https://bit.ly/2w2ZVQT>
- Carmona M, Álvarez M, Marco J, Mahillo B. Organ donation and transplantation activities: 2015 report [Internet]. Madrid: GODT; 2017 [acesso 28 jul 2018]. Disponível: <https://bit.ly/2ZB0LD3>
- Global Observatory on Donation and Transplantation. Organ donation and transplantation activities: 2014 report [Internet]. Madrid: GODT; 2016 [acesso 28 jul 2018]. Disponível: <https://bit.ly/2RmQBTn>
- European Group for Coordination of National Research Programmes on Organ Donation and Transplantation. Project/Contract Number 0011853: Work Package 2: expanding donor pool [Internet]. Madrid: Alliance for Organ Donation and Transplantation; [s.d.] [acesso 17 out 2018]. Disponível: <https://bit.ly/2KmgSu9>
- Life expectancy increased by 5 years since 2000, but health inequalities persist. In: World Health Organization. Newsroom [Internet]; 19 maio 2016 [acesso 17 out 2018]. Disponível: <https://bit.ly/2IOaFdI>
- Espanha. Ministerio de Sanidad, Servicios Sociales e Igualdad. Balance de actividad de la Organización Nacional de Trasplantes en 2017 [Internet]. Madrid: MSSSI; 2018 [acesso 17 out 2018]. Disponível: <https://bit.ly/2IUPECG>
- Espanha. Ministerio de Sanidad, Servicios Sociales e Igualdad. Balance de actividad de la Organización Nacional de Trasplantes en 2016 [Internet]. Madrid: MSSSI; 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2IQeor1>
- Associação Brasileira de Transplante de Órgãos. Dimensionamento dos transplantes no Brasil e em cada estado (2010-2017). RBT [Internet]. 2017 [acesso 17 out 2018];23(4). Disponível: <https://bit.ly/2FWrocl>
- Spain is the world leader in transplants for the 24th year running, according to world transplant registry data held by the Spanish National Transplant Organization. In: Gobierno de España. Acting government [Internet]; 23 ago 2016 [acesso 17 out 2018]. Disponível: <https://bit.ly/2KYJT4T>
- Organización Nacional de Trasplantes. Memoria de actividad de donación [Internet]. Madrid: ONT; 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2XstIsV>
- Israni AK, Zaun D, Rosendale JD, Schaffhausen C, Snyder JJ, Kasiske BL. OPTN/SRTR 2016 annual data report: deceased organ donation. Am J Transplant [Internet]. 2018 [acesso 17 out 2018];18(5):434-63. Disponível: <https://bit.ly/2WNRF3G>
- Moura LC, Silva VS, coordenadoras. Manual do núcleo de captação de órgãos: iniciando uma comissão intra-hospitalar de doação de órgãos e tecidos para transplantes: CIHDOTT [Internet]. Barueri: Manole; 2014 [acesso 17 out 2018]. p. XXXVI. Disponível: <https://bit.ly/1W28KDS>
- Durán BM. Modelo espanhol é referência no mundo. Extra Classe [Internet]. Saúde; 12 set 2014 [acesso 17 out 2018]. Disponível: <https://bit.ly/2MVa5A1>

17. Espanha. Ministerio de Sanidad, Servicios Sociales e Igualdad. La Organización Nacional de Trasplantes celebra su 25 aniversario con pacientes y profesionales de toda la red trasplantadora española [Internet]. Madrid: MSSSI; 2014 [acesso 17 out 2018]. p. 5. Disponível: <https://bit.ly/2lmgYG9>
18. Red y Consejo Iberoamericano de Donación y Trasplante. Actividad de donación y trasplante de órganos, tejidos y células, y recomendaciones aprobadas por el Consejo Iberoamericano de Donación y Trasplante. Newsletter Trasplante Iberoamérica [Internet]. 2017 [acesso 14 out 2018];11(1). Disponível: <https://bit.ly/2RiysX1>
19. Bittencourt C. Brasil e Espanha firmam acordo para troca de experiências em transplantes. UNA-SUS [Internet]. Geral; 12 nov 2014 [acesso 17 out 2018]. Disponível: <https://bit.ly/31AUpW5>
20. Organ donation statistics. Health Resources & Services Administration [Internet]. Statistics & Stories; 2018 [acesso 30 jul 2018]. Disponível: <https://bit.ly/214JUFm>
21. Nothen RR, coordenadora. Sistema nacional de transplantes [Internet]. 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2WWMKY21>
22. Governo investe R\$ 1 bilhão na área de transplante de órgãos. Governo do Brasil. Atenção especializada [Internet]; 20 jun 2018 [acesso 17 out 2018]. Disponível: <https://bit.ly/2KXvaqM>
23. Brasil. Lei nº 9.434, de 4 de fevereiro de 1997. Dispõe sobre a remoção de órgãos, tecidos e partes do corpo humano para fins de transplante e tratamento e dá outras providências. Diário Oficial da União [Internet]. Brasília, 5 fev 1997 [acesso 17 out 2018]. Disponível: <https://bit.ly/2OfMUwp>
24. Brasil. Decreto nº 2.268, de 30 de junho de 1997. Regulamenta a Lei nº 9.434, de 4 de fevereiro de 1997, que dispõe sobre a remoção de órgãos, tecidos e partes do corpo humano para fim de transplante e tratamento, e dá outras providências. Diário Oficial da União [Internet]. Brasília, 1º jul 1997 [acesso 17 out 2018]. Disponível: <https://bit.ly/2KmiURn>
25. Brasil. Decreto nº 9.175, de 18 de outubro de 2017. Regulamenta a Lei nº 9.434, de 4 de fevereiro de 1997, para tratar da disposição de órgãos, tecidos, células e partes do corpo humano para fins de transplante e tratamento. Diário Oficial da União [Internet]. Brasília, 19 out 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2OI2IDT>
26. Brasil. Lei nº 10.211, de 23 de março de 2001. Altera dispositivos da Lei nº 9.434, de 4 de fevereiro de 1997, que “dispõe sobre a remoção de órgãos, tecidos e partes do corpo humano para fins de transplante e tratamento”. Diário Oficial da União [Internet]. Brasília, 24 mar 2001 [acesso 17 out 2018]. Disponível: <https://bit.ly/1W2OL8T>
27. A partir du 1er janvier, tous les Français seront donateurs d'organes par défaut. L'express [Internet]. Actualité; 29 dez 2016 [acesso 17 out 2018]. Disponível: <https://bit.ly/31lcDoH>
28. Holanda transforma todos os seus cidadãos em doadores de órgãos. Veja [Internet]. Mundo; 15 fev 2018 [acesso 17 out 2018]. Disponível: <https://bit.ly/2WQsEVE>
29. Brasil. Projeto de Lei do Senado nº 453, de 2017. Altera o caput do art. 4º da Lei nº 9.434, de 4 de fevereiro de 1997, a fim de tornar explícito que o consentimento familiar, no caso de doação de órgãos, tecidos e partes do corpo humano para depois da morte, só se faz necessário quando o potencial doador não tenha, em vida, se manifestado expressa e validamente a respeito [Internet]. Senado Federal. Brasília, 21 nov 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2XflqyZ>
30. Thomé C, Mengue P. Quase metade das famílias diz ‘não’ à doação de órgãos; 34,5 mil estão na fila. O Estado de S. Paulo [Internet]. Saúde; 11 mar 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2Zwjtf2>
31. CFM atualiza resolução com critérios de diagnóstico da morte encefálica. Conselho Federal de Medicina [Internet]. 12 dez 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2wWLSOY>
32. Conselho Federal de Medicina. Resolução CFM nº 2.173/2017. Define os critérios do diagnóstico de morte encefálica. Diário Oficial da União [Internet]. Brasília, nº 240, 15 dez 2017 [acesso 17 out 2018]. Seção 1. Disponível: <https://bit.ly/2FJqRyo>
33. Associação Brasileira de Transplante de Órgãos. Dados numéricos da doação de órgãos e transplantes realizados por estado e instituição no período: janeiro/junho 2018. RBT [Internet]. 2018 [acesso 17 out 2018];24(2). Disponível: <https://bit.ly/2MUppRx>
34. Saiba quais são os critérios da lista de espera por transplantes. Governo do Brasil [Internet]. Doação de órgãos; 27 set 2016 [acesso 17 out 2018]. Disponível: <https://bit.ly/2XIRAZw>
35. Brasil. Ministério da Saúde. Portaria MS nº 2.600, de 21 de outubro de 2009. Aprova o Regulamento Técnico do Sistema Nacional de Transplantes. Diário Oficial da União [Internet]. Brasília, 30 out 2009 [acesso 19 out 2018]. Disponível: <https://bit.ly/2QVu3IY>
36. Moura LC, Silva VS, coordenadoras. Op. cit. p. 76.
37. Tribunal de Contas da União. Relatório de avaliação de programa: programa doação, captação e transplante de órgãos e tecidos [Internet]. Brasília: TCU; 2006 [acesso 17 out 2018]. Disponível: <https://bit.ly/2x2AP6W>
38. Lima JAF, coordenador. Projeto Pulsar Vida: doação de órgãos e transplantes no Brasil: diagnóstico e diretrizes públicas [Internet]. Goiânia: AmarBrasil; 2015 [acesso 17 out 2018]. Disponível: <https://bit.ly/2WT1jHh>
39. Tribunal de Contas da União. Op. cit. p. 99.
40. Tribunal de Contas da União. Op. cit. p. 97.
41. Tribunal de Contas da União. Op. cit. p. 76.
42. Sistemas integrados viabilizam os transplantes no país. Governo do Brasil [Internet]. Doação de órgãos; 27 set 2016 [acesso 17 out 2018]. Disponível: <https://bit.ly/2WP1r5Q>

43. Brasil. Decreto nº 8.783, de 6 de junho de 2016. Altera o Decreto nº 2.268, de 30 de junho de 1997, que regulamenta a Lei nº 9.434, de 4 de fevereiro de 1997, que dispõe sobre a remoção de órgãos, tecidos e partes do corpo humano para fim de transplante e tratamento. Diário Oficial da União [Internet]. Brasília, 7 jun 2016 [acesso 17 out 2018]. Disponível: <https://bit.ly/2WQZmuY>
44. Doação de órgãos: diretrizes para reduzir contraindicações mal atribuídas. Associação de Medicina Intensiva Brasileira [Internet]. 22 mar 2017 [acesso 17 out 2018]. Disponível: <https://bit.ly/2Im1JwY>
45. Pimentel W, Sarsur M, Dadalto L. Autonomia na doação de órgãos post mortem no Brasil. Rev. bioét. (Impr.) [Internet]. 2018 [acesso 11 fev 2019];26(4):530-6. Disponível: <https://bit.ly/2MTwYni>

**Participation of the authors**

Gustavo Henrique de Freitas Coelho conceived and outlined the project, did the research, collected and analyzed data, and wrote the manuscript. Alcino Eduardo Bonella collaborated with the critical review, data analysis and final writing of the article.

---

Gustavo Henrique de Freitas Coelho

 0000-0001-7075-851X

Alcino Eduardo Bonella

 0000-0002-7910-6961

---



Recebido: 25.10.2018

Revisado: 24. 1.2019

Aprovado: 12. 2.2019