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ORGAN TRANSPLANTATION: LEGAL ASPECTS, BRAIN DEATH PROTOCOL AND OVERVIEW OF THE DONATION-TRANSPLANT PROCESS

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Abstract: Death from circulatory arrest is conceptualized by medicine as the complete cessation of vital activities, while brain death is characterized by the absence of supraspinal motor activity and apnea, the result of an irreversible process, both of which are considered death. This distinction is fundamental, especially in the context of organ donation, where respect for the individual's consent is essential to preserve the dignity of the human body. In Brazil, the public health system (SUS) plays a crucial role in financing transplants, with 96% of procedures being carried out through it in 2018. Transplants can be performed from living donors, usually relatives, or from deceased donors, either due to brain death or cardiac arrest. However, the disparity between the number of recipients and donors' results in organ loss and family refusals, which highlights the need to educate and raise awareness of the population about the donation process. It is essential to reduce underreporting of brain death, face family refusals and adjust contraindication criteria to increase the effectiveness and equity of transplants in the country. This can be achieved through public education programs, awareness campaigns and improving donation and transplantation protocols. This way, we can ensure better use of available resources and save more lives through the generous act of donating organs.
Keywords: Brain death; Organ donation; Transplants; Unified Health System (SUS) and Awareness.

INTRODUCTION

The approach to death within the scope of Law and Medicine is complex and multifaceted. According to Eulâmpio Filho and Jorge Vanrell (2011), Law, as a human creation, does not conceptualize death, focusing instead on regulating the individual's legal personality. Likewise, medicine avoids

conceptualizing death, recognizing it as a sequence of events that culminate in the cessation of vital activities.

The valorization of the corpse today is due to the progress of medical and biological sciences and which, little by little, begins to have greater importance, being considered a true arsenal of organs and tissues of high availability for living individuals or even as an excellent object of scientific study, and must be protected by the Law so that there is not necessarily a sacrifice to the principles of inviolability of the "deceased" or respect for the family of the same.

As for transplantation, it is the process of removing healthy organs or tissues from the donor, followed by implantation in a recipient and aims to save lives or improve quality of life. This process begins with the identification of a potential donor and ends with the transplant itself. The donation/transplantation process is the only area of medical care that cannot exist without the participation of society, and is of great importance to society, precisely because it enables the patient's return to personal activities and the job market and also by increasing survival of those with diseases that compromise the functioning of a specific organ[13.14].

In this context, the present study aims to raise awareness in society about the legal and technical aspects involved in the process of organ donation and transplantation, from the concept of death, bearing in mind that brain death is also death, to the transplant process itself. It is essential that the population understands the importance of the process as a whole, thus aiming to contribute to a more supportive and informed society.

MATERIAL AND METHODS

This article was based on a descriptive and qualitative bibliographic review in English and Portuguese, obtained through the following databases: ScienceDirect, Scientific Electronic Library Online (SCIELO), Google Scholar, Lilacs, NCBI Pubmed, in addition to medical and health, and booklets/recommendations from the Ministry of Health. During the search, the terms "Organ transplantation", "Brain death", "Brain death and transplantation", "Transplantation and laws" were used, using the Boolean operators AND / OR. Inclusion and exclusion criteria were applied to select relevant studies, with special attention to the English and Portuguese languages. The search covered a specific period and followed a defined strategy of searching for articles related to the legal and technical aspects involved in the process of organ donation and transplantation.

RESULTS AND DISCUSSION

According to Eulâmpio Filho, the Law must not attempt to conceptualize death, but rather regulate the termination of the individual's rights by differentiating them from subjects of rights and from those who have rights. This must be taken care of, because, upon acquiring the quality of "de cujus", the individual's body starts to be treated by the Law as a "thing", even before becoming a "corpse" and, the legal concept of "thing" It comes to be, among others, that of "impersonal object, which lacks legal personality" or even "object with autonomous existence, or, suitable object to satisfy human needs or interests".

This legal distinction must be very well defined, because, according to França (2017)3, the valorization of the human body, as a source of tissues and organs, ends up raising certain ethical and legal conflicts, assuming that the human body is legally inviolable and inalienable. França also emphasizes

that, firstly, the consent of the individual, as a donor of organs, tissues or even their body as a whole, is a fundamental part, but not sufficient in itself, to give rise to the lawfulness of the act, there must be an indisputable and imperative necessity for the operation to be legitimized.

Regarding the legality of the rights of family members in relation to the corpse, the author points out that, theoretically, no conflict may arise between the will of the deceased and his or her loved ones, except when the will of one or the other goes against legal provisions or against the morals and good customs, where, generally, the law takes care to favor those closest in accordance with the hierarchy of succession law.

BRAIN DEATH

In 1959, Brain Death (BD) was identified by Mollaret and Goulon as "*coma depasée*", a state of impaired consciousness "beyond coma"4 after a study with 23 patients who presented apneic coma, absence of brain stem reflexes and absence of cerebral electrical signals.

The first criteria for diagnosing brain death were established in 1968 by the Harvard Medical School Committee6, and in 1976, the apnea test was introduced by the Royal College of Medicine in Great Britain, in an attempt to standardize and specify the criteria already used in 1968, in addition to introducing the performance of additional tests in addition to the electroencephalogram.

On March 26, 1968, the surgeon and Professor Euryclides Zerbini performed, in a pioneering way in South America, the first successful heart transplant8, whose proof of death was established through the use of electroencephalogram, following the predetermined criteria, at the request of the team. by Zerbini8,9. During this period there was no legal provision in Brazil, which was quickly resolved with Law Number: 5,479/68, of August 10, 19689. In 1991, the Federal Council of Medicine (CFM), through Resolution 1,396/91.

In 1997, new guidelines were established through new Law Number: 9,434/19974,7. In the same year, the CFM issued new Resolution Number: 1,480/97, replacing resolution Number: 1,396/91, ratifying BD criteria, thus defining BD as an apperceptive coma with the absence of supraspinal motor activity and apnea, a consequence of an irreversible process and of known cause, maintained for six hours in those over two years of age, corroborated by a complementary exam that demonstrates absence of cerebral electrical activity or, absence of cerebral metabolic activity or, absence of cerebral blood perfusion, excluding hypothermia and use of nervous system depressants central.

In 2007, the CFM issued Resolution Number: 1,826/07 establishing and clarifying that "it is legal and ethical to suspend therapeutic support procedures when brain death is determined in a non-organ donor", that "compliance with the aforementioned decision must be preceded by communication and clarification about brain death to the patient's family or legal representative, substantiated and recorded in the medical record" and that "the date and time recorded on the death certificate will be the same as the determination of brain death.

The CFM Resolution Number: 2,173/1711 establishes that procedures for determining brain death must be initiated in all patients who present a deep coma without any reaction to painful stimuli, absence of brain stem reflexes and absence of spontaneous respiratory movements (apnea), known cause of neurological damage, no severe electrolyte or acid-base disturbances, cannot be under the influence of neurodepressant drugs and body temperature must be above 32°C. The

absence of treatable factors that could confuse the diagnosis of BD must be observed, treatment and observation in the hospital for a minimum period of six hours and, in cases of hypoxic-ischemic encephalopathy, the period of treatment and observation must be 24 hours; body temperature above 35 degrees; arterial oxygen saturation greater than 94% and systolic blood pressure greater than or equal to 100 mmHg or mean arterial pressure greater than or equal to 65 mmHg for adults (CFM, 2017).

The brain death protocol (PME) is mandatory, must be initiated regardless of the donor status or not of organs and tissues and its notification is compulsory to the Organ Notification, Procurement and Distribution Center / CNCDO5. It requires two clinical exams to be carried out by different doctors to confirm the non-perceptual coma and the absence of brain stem function, an apnea test to confirm the absence of respiratory attacks after maximum stimulation of the respiratory centers, and a complementary exam to prove the absence of brain activity. The clinical examination must unequivocally demonstrate: Supraspinatus unresponsiveness; Paralytic pupils (II and III cranial nerves); Absence of the eyelid corneal reflex (V and VII cranial nerves); Absence of oculocephalic reflex (III, IV, VI and VIII cranial nerves); Lack of response to caloric tests (III, VI and VIII cranial nerves); Absence of cough reflex (IX and X cranial nerves).

The apnea test will be carried out once by one of the doctors responsible for the clinical examination and must prove the absence of respiratory attacks in the presence of hypercapnia (increase in the partial pressure of CO2 in the blood). And the complementary exam must prove the absence of electrical and metabolic activity of the brain or even brain blood perfusion, namely: Cerebral Angiography, Transcranial Doppler, Electroencephalogram (EEG) or Scintigraphy, Brain SPECT.

DONATION-TRANSPLANT PROCESS

Organs for transplants (including: intestine, kidney, pancreas, liver, lung and heart) and tissues (bone marrow, corneas, skin, valves, bones, muscles, tendons, cartilage, umbilical cord blood, veins and arteries) can be obtained from living or deceased donors, the vast majority of these in brain death (BD), and there is also a growing number, in developed countries, of donors in circulatory death.

Transplant Law Number: 9,434/97, regulated by decree Number: 9,175/17, establishes that organ donation after death can only be carried out when brain death (BD) is confirmed. When due to cardiorespiratory arrest, only tissue donation can be carried out, both after family consent, considering that, according to current Brazilian legislation, family members have the prerogative to decide on organ donation after the death of their loved one, even if the individual has expressed authorization during life. However, the vulnerability of patients urgently waiting for organs suggests the need to review legislation, prioritizing patient autonomy and voluntary consent. This is a normative principle, both constitutional and legal, in addition to representing an ethical and social value that deserves to be duly recognized.

In addition to the transplant law, Decree Law Number: 2268 creates the National Transplant System (SNT) and the STATE TRANSPLANT CENTRALS (CNCDOs), while Ministry of Health/SNT Ordinance Number: 2,600 approves the Technical Regulation of the National Transplant System (SNT). According to this ordinance, the functions of the central entity of the SNT are exercised by the Ministry of Health through the General Coordination of the National Transplant System (CGSNT)[14,17]. Which in turn is assisted by the Strategic

Advisory Groups (GAE), and have the function of developing guidelines, proposing improvements in transplant legislation, identifying quality indicators for donation and transplant activities and issuing opinions when requested by the CGSNT [13,15,17].

Logistical coordination and distribution of organs and tissues for transplants are the responsibility of the Organ Notification, Procurement and Distribution Center (CNCDO); and carried out nationally by the National Transplant Center (CNT), and at state level by the State Health Departments/ State Transplant Secretariat[13,15,17].

Organ Procurement Organizations (OPO) are part of this coordination process, and their creation depends on the CNCDO. They operate on a regional basis in partnership with the Intra-Hospital Organ and Tissue Donation Committees for Transplantation (CIHDOTT), providing continuing education in the area of organ donation; assistance to hospitals in identifying potential donors; and assistance in the brain death (BD) diagnosis process, as well as in completing the donation and transplantation process [13,17,18,19].

CIHDOTT are committees that work with the purpose of improving the identification and maintenance of potential donors; they also have an educational character; and coordinate with the OPO, which, in turn, coordinate with the CNCDO throughout the donation and transplant process[13,17,19].

The process begins after the ME is confirmed, after which the Organ Notification, Procurement and Distribution Center (Transplant Center) is notified and passes the information on to an Organ Procurement Organization (OPO) in the region. The OPO goes to the hospital to evaluate the potential donor[17,18].

The evaluation is structured as follows: clinical history, which seeks to rule out the existence of a disease communicable to the donor, whether infectious or neoplastic, in addition to analyzing the function of the organ to be donated and determining whether there is an indication for additional targeted tests; physical examination, which allows recalling clinical conditions that may contraindicate donation, assessing the compatibility of the dimensions of the organs and verifying their eligibility; complementary exams, which monitor clinical parameters during the maintenance of therapeutic support, identify organic dysfunctions and the existence of communicable diseases; and checking during organ removal surgery, where the intrathoracic and infra-abdominal organs are examined in order to exclude the existence of occult tumors or pathological lymphadenopathies[18,19,20,21].

The OPO informs the CT, which issues a list of registered recipients, compatible with the donor. The center then informs the transplant team and the named recipient patient. It is up to the medical team to decide whether or not to use the organ[17,18,19]. This information will be used to classify donors and help decide which organs and tissues are viable for transplant, in order to minimize risk for the recipient[18,19,21]. As the risk of transmission of infectious and neoplastic diseases cannot be completely eliminated, the absolute contraindication to the use of organs from a potential donor occurs when the risk of transmission exceeds the possibility of benefit to the recipient[21].

The presence of viral infectious diseases, such as HIV, positive serology for HTVL I and II, acute hepatitis, active tuberculosis, malaria, acute viral infections (rubella, rabies, adenovirus, parvovirus), in Brazil is still an exclusion criterion, while in the case of viral diseases other than these, information and consent from the recipient are recommended. Exclusion also applies to donors with a history of clinically uncontrolled sepsis and any malignant neoplastic condition, except carcinoma in situ of the skin, carcinoma in

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situ of the cervix and some primary CNS tumors[21].

When we talk about organ donation due to a stopped heart, the first criterion that we must consider is the irreversibility of the condition, it is necessary to decide the moment in which the application of the necessary resource to reverse the condition is no longer effective, and from then on, this patient becomes a potential organ donor. The medical criteria for inclusion and exclusion of donors due to cardiorespiratory arrest are the same as those used for donors in BD, but it is necessary to understand two factors: the time of ischemia, and the time of preservation of the corpse until the beginning of organ extraction[20].

There are four classifications of donors due to a stopped heart, as follows: I- deceased before arriving at the hospital with known asystole time; II- those who died in hospital after unsuccessful resuscitation maneuvers; III-deceased after withdrawal of mechanical ventilation in a situation of major irreversible neuronal damage and IV-deceased in BD in which asystole occurs before proceeding to extraction. The functional results of organs transplanted from type I and II stopped heart donors are comparable or even better than those from BD donors. This is due to a careful selection of these donors, as they belong to a group of younger donors who have a good prior health condition[20].

CONCLUSION

After the delicate balance between respect for the dignity and will of the deceased, the interests of the family and those of society, an environment conducive to the advancement of biological sciences emerges. Compliance with the norms and protocols established by law plays a crucial role, not only in granting dignity to the deceased patient and preserving their body, but also in mitigating the suffering of family members and offering clear guidance on the possibility of organ donation.

The strict implementation of legal regulations not only protects the individual rights of the deceased, but also contributes to maintaining confidence in the integrity of the health system and the organ donation and transplantation processes. Furthermore, it ensures that the decision on organ donation is made based on ethical and transparent criteria, respecting the autonomy and wishes of the donor, when expressed during life, and not overriding the legal responsibility of his family, who is legally responsible by the donor's body.

In the context of the organ transplantation process, regulatory agencies play a fundamental role in coordinating and improving the quality of potential organ donors and recipients. The adoption of a comprehensive checklist for managing the potential donor after confirmation of death is extremely important. This checklist not only assists in classifying donors based on medical and legal criteria, but also in the careful selection of viable organs and/or tissues for transplantation, aiming to provide maximum safety and effectiveness for the recipient.

It is important to highlight that the quality and efficiency of the organ donation and transplant process depend not only on the technical competence of the medical teams involved, but also on the commitment to ethics, transparency and respect for the individual rights of patients and their families. The continuous review and improvement of protocols and practices related to organ donation and transplantation are essential to guarantee the effectiveness and safety of this process, in addition to strengthening society's trust in the health system as a whole.

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