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ORIGINAL ARTICLE

Donation of organs and tissues for transplantation: Theoretical contributions.

This bibliographic review study aimed to make theoretical considerations related to the process of organ and tissue donation for transplantation in Brazil. The information source was composed of relevant publications from the Brazilian Association of Organ Transplants, as well as articles found in Latin and American databases, in addition to the current legislation. The increase in the donation rate depends on a broad and systematic look at the technical and legal issues inherent to the donation process. To strengthen this process, it is recommended to incorporate the social approach and the ethical perspective, based on technical and legal understanding and respect for the right of autonomy of potential donors and their families. Actions that ensure ethical-legal management presuppose a commitment to the quality and safety of the donation process, which must be strictly pursued by professionals in this context.
Doação de órgãos e tecidos para transplante: Contribuições teóricas.

Este estudo, de revisão bibliográfica, objetivou tecer considerações teóricas relacionadas ao processo de doação de órgãos e tecidos para transplante no Brasil. A fonte de informação foi composta por publicações relevantes da Associação Brasileira de Transplantes de Órgãos, bem como artigos encontrados em bases de dados latino e americanas, além da legislação vigente. O aumento da taxa de doação depende de um olhar amplo e sistemático acerca das questões técnicas e legais inerentes ao processo de doação. Para o fortalecimento desse processo recomenda-se incorporar a abordagem social e a perspectiva ética, baseadas no entendimento técnico e legal e no respeito ao direito de autonomia dos potenciais doadores e seus familiares. As ações que asseguram um manejo ético-legal pressupõem compromisso com a qualidade e segurança do processo de doação, que deve ser rigorosamente perseguida pelos profissionais nesse contexto.

Palavras chave: Obtenção de Tecidos e Órgãos, Transplante de Órgãos e Tecidos.
INTRODUCTION

The donation process is defined as a set of actions and procedures that manage to convert a Potential Donor (PD) into an effective donor. PD is any patient whose brain-oriented therapy has been assessed as ineffective or brain death (BD) is imminent or has already been established. Organ donation can also be done during life for a family member or friend, after the donor’s clinical evaluation. In this case, blood compatibility and no risk to the donor are paramount [1].

Transplantation is the partial or total removal of a body structure or organ and its implantation in the same person or in another individual. It is described as a procedure that provides rehabilitation and increased life expectancy, currently recognized as an effective therapy in the treatment of several chronic and disabling pathologies [2].

The organs and tissues that can be removed in life are kidney, part of the pancreas, part of the liver, part of the lung, bone marrow and skin. The living donor is any person who is in good health and who agrees with the donation, constituting an intervening donation, a process carried out between relatives up to the fourth degree and / or spouses, and in the case of unrelated individuals the law allows the donation be carried out only with judicial authorization [1].

In Brazil, the first transplant with a cadaver donor was a kidney transplant and occurred in 1964 in Rio de Janeiro. The notification of DPs took place initially in a poorly structured manner, so that in the 1980s, the states of Rio de Janeiro, São Paulo and Rio Grande do Sul began to organize such notifications [3].

The first Brazilian law to regulate organ transplants was Law No. 4,280 / 1963, which was repealed by Law No. 5,479 / 1968. This law established the criterion of informed consent, in which the decision on the donation belonged to the family members of the PD [4].

The procurement of organs and tissues for transplantation in Brazil is currently regulated by Law 9.434 / 97, known as the transplantation law, which deals with legal issues related to the removal of organs, tissues and parts of the human body for purposes of transplantation and treatment. Decree-Law nº 2.268 / 97 creates the National Transplant System (SNT) and the Organ Notification and Collection Centers (CNCDO) with implantation in all States of Brazil, decentralizing the donation and transplantation process and defined the donation presumed as a form of consent [5].

CNCDO’s or State Transplant Centers (CET’s) are the executive units of the SNT’s activities, responsible for coordinating transplantation activities such as: promoting the registration of potential recipients, with all the information necessary for their quick location and
compatibility verification. for transplantation, classify the recipients and group them in the order established by the registration date, communicate the registrations to the SNT central body and organize the national list of recipients, receive death notifications, determine the referral and arrange the transport of tissues and organs taken from the authorized health establishment [5].

It is worth noting that the ordinances of the Ministry of Health (MS) No. 1,262 / 2006 and 2,600 / 2009 refer to the technical regulation of the transplant system, to establish the attributions, duties and efficiency indicators and the potential for donation of organs and related tissues to Intra-hospital Organ and Tissue Donation Commissions for Transplantation (CIHDOTT’s) [6].

Regarding the presumed donation, the citizen who opposed the donation, needed to register the expression: “Non-organ and tissue donor” in some identification document (RG) or national driver’s license (CNH). In this understanding, any Brazilian who did not register this negative in life was considered a PD. In this context, the presumed donation did not find support in Brazilian society and, therefore, provisional measure No. 1,718 of October 6, 1998 was subsequently published, which made family consultation mandatory for authorization of donation [5]. Thus, law No. 10,211, published in March 2001, defined informed consent as a form of manifestation to the donation, passing the removal of tissues, organs and body parts of deceased people for transplants or other therapeutic purposes, depending on the spouse's authorization. or relative of legal age, obeying the succession line, straight or collateral, up to and including high school, signed in a document signed by two witnesses present at the death verification [7].

Currently, organ and tissue transplantation constitutes a safe and effective therapeutic alternative in the treatment of various terminal diseases, leading to improvements in the quality and outlook of society. This became possible due to the improvement of surgical techniques, development of immunosuppressants and immunological understanding of compatibility and rejection. In the meantime, organ and tissue transplantation is no longer an experimental treatment and has become an extremely effective procedure in the control of the terminal insufficiencies of some organs and the failure of some tissues [8].

In the first half of 2015, in Brazil, for the first time since 2007, there was a decrease in the rate of PD’s, effective donors and the number of kidney, liver and pancreas transplants, compared to the previous year. The high rate of family refusal to donate (44%) persists as the main obstacle to making the donation effective in most States, while in others the difficulty in carrying out tests for the diagnosis of BD persists [9].

Currently, we are experiencing a reality permeated by difficulties, especially with regard to the low number of transplants performed in Brazil, despite all the advances in this therapeuti
field [6]. Today, Brazil has one of the largest public programs for organ and tissue transplants in the world, with approximately 548 health establishments and 1,376 medical teams authorized to perform transplants. The SNT is present in 25 states of the country, through CETs. Advances in this therapeutic field are undeniable, however, the growing disproportion of the number of patients on the list versus the number of transplants performed is an unquestionable fact, in which, among the limiting factors, there is the non-notification of patients diagnosed with BD to the CNCDO’s, despite its mandatory provision under the law, as well as the lack of a permanent education policy for health professionals regarding the donation and transplantation process [10].

BD is a state in which brain function is disrupted, in which the causal factor is recognized and is considered irreversible. The American Association of Neurology (AAN) defined ME based on three cardinal signs, which are the absence of brain functions, including the brain stem, coma and apnea. This situation is an essential condition for post-mortem extraction of organs and tissues [11].

Death for a long time was conceptualized by the absence of heartbeat or spontaneous breathing movements. After years of study, some countries have defined BD as a total and irreversible stop in the functioning of the entire brain, based on neurological criteria, which allows the family to decide whether to donate organs and tissues for transplantation purposes [12].

BD, in most cases, is associated with traumatic, congenital or acquired causes that lead to unexpected hospitalizations. In this way, families are exposed to the possibility of death suddenly. In addition, many of these patients are in good health, which makes it even more difficult for the family to accept death and interfere with the decision regarding a possible donation [11].

The maintenance of the PD requires dedication and technical competence of the assistant team, because, during the BD process, a series of physiological changes occur, contributing to the patient's instability. In this context, although organ and tissue transplantation is a safe and effective therapeutic alternative, leading to improvements in quality and outlook on life as mentioned above, there is a race against time to become a PD, with all the hemodynamic instability that ME causes an organism in an effective donor [12].

To be a donor, it is not necessary to leave a written document. It is up to the family to authorize the withdrawal after the death is confirmed. However, there are still doubts, myths and prejudices regarding the transplantation of human organs. Organ donation is a controversial topic and has aroused interest and discussion in various segments of society.

The lack of clarification, the sensational news, the absence of permanent programs aimed at
sensitizing the population and encouraging organ procurement contribute to make the process more difficult [10].

It is described that the reception of the patient and his family in the hospital, the recognition of BD, the adequate family interview and the clinical maintenance of the PD are fundamental to reduce this disproportion [3].

The preparation of the family begins the moment the patient enters the hospital, as aspects such as honesty and the team's commitment to this family will provide positive results later. The interview for possible donation is facilitated when the family realizes the effectiveness and commitment of the team during patient care [12].

The success of the family interview depends mainly on the predisposition to donation, quality of hospital care received, ability and knowledge of the interviewer. And the necessary conditions for the family interview are: knowing the conditions of the PD and the circumstances surrounding his death, talking to the attending physician, identifying the best person to offer the possibility of donation, in addition to a quiet and comfortable environment [13].

Despite all this effort, today, as well as in the beginning, the issue of the difficulty in obtaining organs is faced. The question is, surrounded by a tangle of other complicators. Organ donation is on the agenda of both formal discussions between health professionals and questions from society. Therefore, it involves legal aspects that support the donation and the activity of the health professional; it involves ethical and moral aspects; the need to make donation a matter of public knowledge [14].

We understand that the topic of organ transplantation certainly has characteristics that differentiate it from any other health issue. Firstly, because it is not restricted to the relationship between the health team and the patient and his family. There is a direct dependence on a third element, the organ donor. In this understanding, despite the fact that transplants are based on effective technical procedures and with undeniable technological advances, it cannot occur without a donor. For public understanding and acceptance of organ donation and transplantation by the community, it is important to note that many socio-cultural changes are necessary.

We believe that the donation of organs and tissues for transplantation is a process permeated with people's moral, ethical and religious values, raising in individuals reflections about finitude and the relationship with the body after death. Given the above, the study aimed to make theoretical considerations related to the process of organ and tissue donation for transplantation in Brazil.
METHODS

This is a study of narrative literature review. The source of information was composed of relevant publications from the Brazilian Association of Organ Transplants (ABTO), as well as articles found in Latin and American databases, in addition to current legislation, to achieve the objective proposed in this study.

The texts found were read, organized and synthesized in four thematic categories, namely: Considerations regarding donation and transplantation of human organs and tissues, diagnosis of brain death, shortage of organs for transplantation and the role of nurses in the donation and transplantation process.

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RESULTS AND DISCUSSION

Considerations regarding the donation and transplantation of human organs and tissues

Donation and transplantation of human organs and tissues are controversial topics that have aroused interest and discussion in various segments of society. The lack of clarification, the sensational news on organ trafficking, the absence of permanent programs aimed at raising awareness among the population and health professionals and encouraging the donation of organs and tissues for transplantation contribute to feed doubts and to deepen myths and prejudices [15 ].

The success of transplants depends on the organization and effective participation of multiprofessional teams in the entire donation process; thus, the actions of BD diagnosis, notification and adequate maintenance of the PD are indispensable to reduce mortality on the waiting list [9].

The donation process (figure 1) begins with the recognition of the PD, this recognition must start from systematic visits made by professionals who work in the organ search service, mostly nurses, in the inpatient units that have the greatest possibility of notification PD, such as Intensive Care Unit (ICU) and Emergency Room [16].

Figure 1: Organ and tissue donation process for transplantation in Brazil.
Although doctors and nurses are given the greatest share of responsibility and authority for being the professionals responsible for all phases of the donation process, the participation of other professionals who can act in an eventual or systematic way is essential: physiotherapist, nutritionist, pharmacist, psychologist, social worker and others [6].

There are two types of organ and tissue donors: living donors that refer to the healthy individual who is willing to donate one of the even organs (kidney) or part of them (liver, lung), and cadaveric or deceased donors. To be considered a post-mortem donor, the individual must be diagnosed with BD, or have had a recent cardiorespiratory arrest (CRP) from which it is possible to remove some organs, especially the kidneys. Or even have a diagnosis of late CRP. It is a corpse with a recent stop (up to 6 hours) that can donate only tissues [17].

BD is defined as the total and irreversible arrest of brain stem and hemisphere activity, regulated by Resolution No. 1480/97 of the Federal Council of Medicine (CFM), requiring two neurological clinical examinations and a complementary graphic examination for its verification [18].

Considering that the total and irreversible interruption of brain functions is equivalent to the person's death, in these cases the cardiorespiratory function is maintained through devices and pharmacological support to enable the family to decide on the donation of organs and tissues for transplantation [19].

It is possible to classify individuals in BD as to the ability to donate in two terms, the possible organ donor, which corresponds to the individual with neurological injury of any kind (trauma, stroke, anoxic encephalopathy after PCR etc.) in an apprehensive coma (score three points on the Glasgow coma scale), and the potential organ donor (PD), which corresponds to the individual diagnosed with BD, notified for a CET1.

Brain death diagnosis
According to history, it was in 1959 that some groups of French neurologists had their first conception of BD, due to the clinical condition of the dead brain in a living body, called at the time of coma dépassé.20

In the United States of America (USA), a presidential commission was created in 1981 after a period of dialogue on this topic, which defined death as the irreversible cessation of circulatory and respiratory functions or the irreversible cessation of the functioning of the entire brain.21

In 1995, AAN published a review of the medical literature associated with classification, based on scientific evidence from more than 200 articles on BD that made it possible to define the criteria currently used. A single case of recovery of any cortical and brainstem function has never been demonstrated or reported after the diagnosis of BD using the 1995 ANA criteria.22

In Brazil, the diagnosis of BD is confirmed through two clinical examinations and a complementary examination, as determined by law No. 9,434 and CFM Resolution No. 1,480 / 97. The clinical examination must be performed with an interval of time according to the age group of the PD: a) from seven days to two incomplete months, repeat the exam every 48 hours; b) from two months to an incomplete year, repeat every 24 hours; c) from one year to two years incomplete, repeat every 12 hours and above two years, repeat the exam with an interval of 6 hours.22 In this context, before an individual in BD, family members are able to decide whether or not to donate organs and tissues for transplantation purposes. We reiterate that, in the event of a family refusal, CFM Resolution 1.826 / 2007 defines the legality and ethical character of the suspension of therapeutic support procedures when determining the BD of the non-donor.22

It is important to emphasize that clinical examinations must be performed by different medical professionals, who cannot be members of the removal and transplant team, and that an examination must be performed by a neurologist, neurosurgeon or neuropediatrician with experience in neurological examination.3

The complementary exams for the diagnosis of BD should show brain inactivity due to the absence of blood flow, electrical activity or metabolic activity through the exams: electroencephalogram, Transcranial Doppler, cerebral oxygen extraction, cerebral angiography, radioisotopic scintigraphy, xenon computed tomography, tomography by xenon single photon emission, positrons and intracranial pressure monitoring. These can be performed between the first and the second exam or after the second clinical exam.22

From a legal and medical point of view, BD corresponds to death, even if its cardiological and pulmonary conditions are artificially maintained. Therefore, the time that must appear on the
death certificate is the time of confirmation by complementary examination of BD. And even when all support is maintained, cardiac arrest occurs for about a week [23].

A novelty in the registration in 2016 was the inclusion of data from eligible donors. In the first quarter of 2016, with the exception of the State of São Paulo (data not sent), that of the potential donors notified (1,767), 72% had their diagnosis of BD confirmed, becoming eligible donors, and that 38% (481) of these became effective donors. It is inferred, then, that it is more difficult to obtain the donation than to confirm the diagnosis of BD, which was the great problem of many States some years ago [24].

**Shortage of organs for transplantation**

Factors that limit organ donation are: lack of identification and notification of a DP; inadequate care for the donor; needs for confirmatory EM exams; inadequate family interview; family members who refuse to donate 30.0% to 40.0% of the time; difficulties in contact with the transplant teams; problems in the removal and distribution of donated organs [23].

Countless researches point to the need for training and qualification of the professional responsible for conducting the family interview [7].

The CNCDOs of the Brazilian states have shown concerns about the ability to identify PD, through quantitative studies of PD due to violent death, which could supply the need for organs if the transplant was carried out. They also concluded that there is no shortage of PD, but failure to detect them and make the donation effective [5].

Despite the advances, the lack of notification of BD and the failures in the maintenance of organs for collection still represent factors that hinder the effectiveness of the donation and transplants [6].

The crisis in many sectors of the country, including health, seems to have also affected donation and transplantation. In the first quarter of 2016, there was a drop not only in relation to growth forecasts, but, worryingly, compared to 2015. The effective donor rate, for example, in 2015 was 14.1 pmp (per million population), and the forecast for 2016 was 16 pmp, with the rate obtained in the first quarter of 2016 being 13.1 pmp, 7.1% less than in 2015, 18.1% below the forecast. The donation effectiveness rate (28%) was 4.8% lower than the previous year (29.2%) and 12.5% below the forecast (32%). Another worrying aspect is that the three most populous states, responsible for 40% of the inhabitants, had a drop in the donation rate: SP (8.2%) MG (19.6%) and RJ (18.5%). One encouragement, however, is that almost all states, with the exception of Amapá, are already notifying DPs, although some have failed to effect them. Among the four highest donation rates are the three southern states, SC (30.5 pmp), RS (25.2 pmp) and PR (22.2 pmp), and the DF (28.8 pmp) [24].
The difficulties presented for the potential effectiveness of the transplant are registered in numbers through the annual chart, containing the number of transplants performed in the period 2006 to 2016 of the main organs highlighted below (figure 2).

**Figure 2**: Historical series of the number of Transplants performed in the period from 2006 to 2016.

![Absolute number of transplants (annual)](image)

Source: ABTO (2016)24

**Nurse's role in the donation and transplantation process**

Since the first transplant in Brazil in 1965, the nursing team has always been present, but only in 2004, through Resolution No. 292/2004 of the Federal Council of Nursing (COFEN), its field of professional action in this area was defined [23].

In the meantime, we consider it important to identify the elements of the nurse's work process with the PD patient of organ and tissues and their family that may interfere with the donation and transplantation process [25].

We understand that it is the responsibility of the nursing team to recognize, detect and identify the PD in BD, in addition to controlling all hemodynamic data. Nursing care for a body of a PD in BD or an individual with a stopped heart must be provided with dignity and respect, regardless of the procedure to be followed. We believe that guidance and disclosure about the donation process should take place in health establishments and for society in general, as part of the nurse's actions. These attitudes are expected to demystify the problem surrounding the donation of organs and tissues, through the socialization of information.

It is necessary that the professional nurse and his team are trained and qualified for this
purpose, showing understanding, offering help to patients and family members when requested, providing more human relations based on the principle of bioethics, taking into account the principle of autonomy and respecting whatever the family decision [6].

Therefore, it is extremely important that the family actively participate in the process or that they appoint a legal representative to accompany all procedures, highlighting the transparency of the process. The nurse is present alongside the PD's relatives and precisely because of this, they perceive their needs helping to understand this new reality as it presents itself [7].

CONCLUSION

The increase in the donation rate depends on a broad and systematic look at the technical and legal issues inherent in the process of organ and tissue donation for transplantation. To strengthen this process, it is recommended to incorporate the social approach and the ethical perspective, based on technical and legal understanding and respect for the right of autonomy of the DPs and their families. The actions that ensure ethical and legal management, defined in the transplantation legislation in Brazil incorporated in the present study, presuppose a commitment to the quality and safety of the organ and tissue donation process, which must be strictly pursued by the professionals who work in this context. The transplant depends on the effectiveness of the donation process, which is divided into interdependent stages and which need to be well executed and articulated with each other.

As for the problems that interfere in the development of this process, it was found the existence of underreporting of PDs, deficiency of infrastructure to carry out the diagnosis of BD and maintenance of the PD, deficiency of knowledge of the BD criteria by health professionals and refusal of family members to the donation. A successful transplant depends almost exclusively on the success of the donation process, from the moment of detecting the PD, maintaining the PD, family interview, capturing the organs and tissues until their implantation in the recipient. There are numerous factors that limit the progress of organ donation, and to change this situation, joint actions involving health professionals, educators and society in general are necessary, with the aim of promoting discussions, clarifying doubts and consequently reducing the number of deaths on waiting lists for a transplant. We hope, therefore, that these attitudes build a positive culture about donation in the country, contributing, in the long run, to the increase in donation rates in the country. Thus, we consider it urgent to increase studies that reveal the difficulties that permeate this process and that can help professionals in this context.

INTEREST CONFLICTS

The authors declare no conflicts of interest
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