Process of Organ Donation and Tissue in Hospital Units

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Abstract

Background: To describe the process of organ and tissue donation for transplantation in hospitals in the northeastern of Brazil.

Methods: This is a quantitative, descriptive, prospective study with 65 potential donors, using a structured script of non-participant observation and institutional documents. Data were analyzed using descriptive statistics.

Results: There were 65 potential of donors, 59 (90.7%) of them underwent laboratory tests to evaluate the functioning of the organs, 49 (75.4%) were evaluated regarding the diagnosis of Brain Death (BD), 37 (56.9%) families were interviewed, 20 (30.7%) of them authorized the donation and 18 (27.7%) had their organs donated. In the donation process, the steps of evaluation, maintenance and diagnosis of BD presented the biggest problems.

Conclusions: It was identified that several procedures of the donation process were weak, contributing to low effectiveness. These data support the planning of actions related to organ donation, enabling reflexive action on the process.

Keywords
Nursing; Obtaining Tissues and Organs; Encephalic Death; Transplant.

Introduction
The scientific, technological, organizational and administrative advances have allowed organ transplantations are becoming a safe and saving therapy for patients with different types of terminal illnesses. However, the common problems to all countries are the dispropor-
tionate increase of a list of patients waiting for donors, causing the death of many individuals who are hoping for an organ, tissue or cells to save their lives [1-3].

It is known that transplantations are complex procedures requiring material resources and specialized people, high-level technical training and continuing education, concerned with the transfer of an organ, tissue or cell of living or dead donor for a sick person who is called the recipients. This treatment aims to improve the quality and perspective of the life of patients who need this therapy to survive [4-5].

The transplantation effectiveness with a dead donor fundamentally depends on the donation process, that is the dynamics of systemized and interrelated actions, beginning with the identification and notification of an individual in an apperceptive and non-apperceptive coma with a score of 3 on the Glasgow Coma Scale. Then, it is necessary to a careful clinical and laboratory evaluation, resulting in no contraindications identification representing a risk to recipients. Thus, during the donation process, the maintenance of the Potential Donors (PD) should be performed for the hemodynamic stability, feasibility and quality of organs and tissues which may be used [6].

In the meantime, the next step is the diagnosis of Brain Death (BD), respecting the guidelines of Resolution Nº 1,480/97 of the Federal Council of Medicine (FCM) [7]. It is noteworthy that this can only be performed after notification to the family on the death of the patient, a family interview by a trained professional who will seek the consent for the donation [8].

If there is family agreement, the professional in charge of the donation process and the Notification Center, Procurement and Organ Donation for Transplantation (NCPDODT) began to consider other factors for the effectiveness of the donation, with the implementation of the default logistics [6]. Before starting the capture of organs and tissues, the doctor should create a Death Certificate in natural death situations. In the cases of death from external causes, regardless of the donation, this professional must send the body to the Legal Medicine Institute, which will hold the autopsy and the Death Certificate [9].

Thus, it is noticed that this process requires speed, skills and the ability of the professionals involved, due to the progressive loss of function of organs after the diagnosis of BD. Given the complexity involved in the donation process, its planning requires experience and capacity of the health team members to consider the needs of patients and their families and respect the rules and laws governing the development of the stages [6, 10].

The nurse is among the multidisciplinary team involved in the donation process, with participation in the different stages of this process, based on Resolution Nº 292/2004 of the Federal Council of Nursing as a legitimate area of professional action in this care area. Thus, it is privately up to the nurse: to plan, execute, coordinate, supervise and evaluate nursing procedures for both the donor organ and tissue as the recipients and their family members [11-12].

There is also the requirement and ability to handle critical situations quickly and accurately, competence in information integration, construction of judgments and priorities setting. Therefore, under the coordination of the nurse, the nursing staff should provide a high level of service to both donors and the transplant recipients and their families or caregivers [12].

In this context, it is believed that studying how the process of organ and tissue donation for transplantation is developed, becomes necessary to detect any weaknesses in any phase of its development, both in terms of procedure aimed at detecting the PD, physiological maintenance of organs, as in actions involving the collection and distribution of organs that may interfere with the donation. Also, there is a lack of national surveys to assess the process of
organ donation in its entirety because when they are done, they are focused on a phase or process problem in isolation, and not all stages, as this study aims to do.

Supported by these considerations, the question is: How is the process of organ and tissue donation for transplantation developed in hospitals in the northeastern of Brazil? Faced with this question, the objective is: to describe the process of organ and tissue donation for transplantation in hospitals in the northeastern of Brazil.

Methods
This is a descriptive and prospective study with a quantitative approach, conducted in six hospitals of the Northeast Brazil, three of them were public, and three of them were private hospitals, all accredited by the National Transplantation System and the NCPODT and Procurement Organization of Organs (POO) in that region.

The study population was all DPs identified and notified to the POO from August 2012 to February 2013, which is the data collection period. The random sample was calculated without replacement from the annual average (81.4) of the PDs assisted in the six institutions during 2005 to 2009. Therefore, the formula for calculation of samples for the finite population was used.

For the selection of PDs, the following inclusion criteria were adopted: score 3 on the Glasgow Coma Scale; cause of coma defined by computed tomography; identification of the donor and a family member that could be responsible for authorizing or not the donation. The exclusion criteria were: evidence of communicable diseases, cancer, and injecting drug use detected before the opening of BD protocol and neurological improvement.

Thus, based on the selection criteria and sample calculation, there were 65 PDs included to be followed. However, during this study, three PDs were excluded, one because he was without identification and two for having improved clinical and neurological status before the opening of the BD protocol.

The data collection instrument was developed based on the fundamental recommended by the scientific literature [6-7, 13-16], set up in a structured script non-participant observation, checklist type, composed of the following parts: personal identification data; data on the donation process related to the identification, notification, assessment and maintenance of PD, diagnosis of BD, family interview, documentation, logistics, information about the collection and results of the donation.

It is noteworthy that the instrument used to collect data from this research was subjected to a pre-test of the Incubator Nursing Procedures research group of the Federal University of Rio Grande do Norte.

For this study, the concepts considered for each stage and their parameters are shown in Table 1.

Table 1. Parameters used for the evaluation of the care stages to potential donors of organs and tissues for transplantation, 2016.

| Stages | Exams / care | Parameters |
|--------|--------------|------------|
| Laboratory Evaluation | Performed once | Blood typing and serology [15]. |
| | Performed daily | Complete blood test; Electrolytes: Sodium and potassium; lung function: blood gas analysis; cardiac function: creatine kinase isoenzyme enzymes creatine kinase MB; Renal function: urea and creatinine; liver function: aspartate aminotransaminase, aminotransaminase alanine, gamma glutamyl transferase, total bilirubin and direct bilirubin; pancreatic function: amylase and glucose [14-15]. |
| | Opening of the Protocol or, if necessary | Microbiological cultures [6, 14]. |
Regarding the result of the donation process, it was observed that non-donation causes, the number of donors, organ/tissue donations and obtained [6, 15].

It is noteworthy that it was previously requested the authorization to the institutional coordination of NCPODT, POO and boards of hospitals to carry out this research. After this procedure, data collection took place through non-participant systematic observation and institutional documents with cases and records. Therefore, the consent of the spouse or second degree relative of the PD was requested to participate in the study by signing the informed consent form.

It is highlighted that the data collection was carried out in NCPODT, POO, and six hospitals during 24 hours a day, seven days a week, with a team composed of researchers and five nursing students previously trained. They took turns in three shifts, with scales of 6 and 12 hours. Upon notification of the PD to the POO, the data collection team observed the development of the donation process stages without taking any interference.

Data were analyzed using descriptive statistics and presented in a Table 2 and Figure 1. To this end, the Microsoft Excel 2010® software and SPSS 20.0 program were used.

The research followed the ethical and legal aspects according to Resolution 196/96 of the National Health Council. The study had a favorable opinion of the ethics committee on research at the Hospital University Onofre Lopes and approved under the General Certificate for Ethics Assessment Nº 007.0.294.000-10.
Results

With the aim of better understanding the study, the results were presented in three stages: socio-demographic characterization of the PDs of organs and tissues for transplantation; the process of organ and tissue donation; and evolution and outcome of the process of organ and tissue donation.

Socio-demographic characterization of the PDs of organs and tissues for transplantation

When characterizing the socio-demographic profile surveyed, it was found that most of the subjects were male (n=33; 50.8%), aged up to 45 years old (n=35; 53.8%), mean age of 42.3 years old, minimum of 5 and maximum of 73 years old (± 17.32 years old), single/widowed/divorced (n=37; 56.9%), with level of education to complete primary education (n=39; 60.0%), with a professional activity (n=56; 86.2%), Catholics (n=54; 83.1%); and residents in the metropolitan region of Natal/Rio Grande Norte (n=34; 52.3%).

Process of organ and tissue donation

Regarding the identification and notification of the PD, it was observed that out of six hospitals with the DPs followed, all were accredited by the National Transplantation System for the removal and transplantation of organs and tissues. As for the hospital sector, 42 (64.6%) of the PDs were in the Intensive Care Unit and 23 (35.4%) in the emergency department. In the diagnosis, the stroke predominated in 33 PDs (50.8%), followed by cranial trauma (n=26; 40.0%). The other causes were wound by firearm (n=3, 4.6%), anoxic encephalopathy (n=2, 3.1%) and brain tumor (n=1, 1.5%). The average time between the identification and notification of the PD was less than 12 hours.

Regarding the laboratory tests, most PDs performed the blood typing (n=58; 89.2%), tests for hematological evaluation (n=52; 80.0%), evaluation of electrolytes (n=52; 80.0%), renal function (n=52; 80.0%) and lung function (n=46; 70.8%). Serology was performed in 20 (30.8%) PDs whose family signed the donation form. However, the tests were performed for the evaluation of pancreatic function in 24 (24; 36.9%) DPs, heart function in 16 PDs (24.6%), liver in 11 PDs (16.9%) and microbiological culture in one (1.5%).

It was observed that the parameters were appropriate in greater proportion in hematological function in the maintenance of physiological functions of the PDs (n=55; 84.6%), and the maintenance of the temperature body was done only in 31 (47.7%) patients, as shown in the Table 2.

Table 2. Maintenance of the organic functions of organs and tissues potential donors for transplantation, 2016.

| Potential Donors Maintenance               | n=65 | %   |
|-------------------------------------------|------|-----|
| Hematologic function                      | 55   | 84.6|
| Cardiovascular function                   | 51   | 78.5|
| Respiratory function                      | 49   | 75.4|
| Endocrine and metabolic function          | 47   | 72.3|
| Liver function                            | 46   | 70.8|
| General care                              | 45   | 69.2|
| Renal function                            | 38   | 58.5|
| Corneas care                              | 37   | 56.9|
| Electrolytes Balance                      | 36   | 55.4|
| Infection Control                         | 35   | 53.8|
| Body temperature                          | 31   | 47.7|

Regarding the BD diagnosis, the cause of coma in the 65 PDs has been identified. The complementary examination was performed in 51 DPs (78.5%) using the TCD in 31 (60.8%), the Electroencephalogram in 17 (33.3%) and arteriography in three of them (5.9%). The causes of non-realization of further examination in 14 (21.5%) PDs included: no opening of BD protocol (n=13; 92.9%) and heart failure (n=1, 7.1%). The two neurological evaluations were performed in 49 PDs (75.4%). However, in 52 of them (80.0%), the protocol was initiated, and the doctor only held the first evaluation in three DPs (4.6%). From 16 DPs (24.6%) that have not performed or completed the two neurological evaluations, there were eight (50.0%) cases related to cardiac arrest,
five (31.3%) hypothermia and three (18.7%) cases where the doctor told the POO professional not knowing to take the exam.

In most cases (n=46; 70.8%), there were PDs with the optimum temperature. However, in 4 (8.2%) of the 49 DPs that have carried out two neurological evaluations, the BD evaluation protocol was completed with the temperature below 35°C. Other items evaluated were: time between the removal of sedation and early opening of BD protocol; the 52 PDs in which the protocol was opened, the time was considered appropriate in 39 times (75.0%). It is noteworthy that in 13 (25.0%) patients, the time was higher than necessary.

On the 52 neurological evaluations performed, there were 33 (63.4%) testing all reflexes to evaluate the involvement of the brain stem. However, 19 (37.6%) tests were not conducted by Resolution Nº 1,480 FCM, and even then, it was continued with the BD protocol. Of that 49 who underwent the first and second evaluation, the time was greater in most PDs (n=27; 55.1%). Among the 51 patients who had the complimentary exam, the BD was not confirmed in four (7.8%), and in all these cases, the BD protocol was suspended, and new evaluations were not resumed.

In the family interview, 37 (56.9%) family members were interviewed and 20 (30.8%) authorized the donation. It was found that the intensive care doctor gave information and clarified doubts about the progress of treatment, current state of the patient and diagnosis of BD in 33 (89.2%) times. In 36 (97.3%) times, the interview took place after the confirmation of the BD diagnosis, communication about the diagnosis to the family by the intensive care doctor, gathering information about the PD in the medical record and the health team. In 100% of cases, the interview took place in a calm environment, with accommodations for all family and friends who were interested in participating. Therefore, the professional POO proved to be prepared for the procedure, used simple language, explained about the diagnosis of BD, the sequence of events and that receptor would not be identified. As for the relative responsible for the donation, 100% of the time was by law.

In the documentation of BD, most of the 49 PDs (n=42; 85.7%) in which the protocol was completed, died or referral statement for the Scientific-Technical Institute Police (STIP) were not filled after the completion of the final examination (neurological or complementary) to the time of completion of this well specified.

As regards logistic aspects, the adaptations occurred in 100% of cases for equipment and materials needed for the procedure capture and transport of organs and tissues. The scheduling of the operating room, as well as coolers, solutions for cryopreservation and ice were provided by professionals from the POO.

**Progress and outcome of the donation process**

The Figure 1 shows the evolution and outcomes of the process of organ and tissue donation for transplantation. It was observed that, in the 65
PDs identified and notified, there were 59 (90.7%) conducted in the laboratory tests to evaluate the functioning of the organs, with their maintenance; 49 PDs (75.4%), were carried out neurological evaluations and examination to confirm the diagnosis of BD; 37 (56.9%) family member of the PDs were interviewed, 20 (30.7%) authorized the donation, and 18 (27.7%) PDs had donated organs and collected.

Regarding the causes of not making the diagnosis of BD, there were eight (50.0%) cardiac arrest; five (31.3%) hypothermia; and three (18.8%) cases where the doctor did not make the diagnosis. The causes of the 47 (72.3%) PDs not donated were: refusal of relatives to make a donation (n=17; 36.2%); not finished protocol for the diagnosis of BD (n=16; 34.0%); medical contraindication (n=11; 23.4%); and cardiac arrest (n=3, 6.4%).

Thus, it was found that the best medical contraindications were: age (n=3; 27.3%), positive serology for hepatitis C and Chagas disease (n=2; 18.9%) and viral encephalitis (n=2; 18.9%). Other contraindications consisted of diabetes mellitus, brain tumor without biopsy, injecting drug user and thrombocytopenia clarifies, both present in one case. Of the 18 PDs that implemented the donation, it was observed that, from the 27 organs donated and collected, 18 (66.7%) were kidneys; eight (29.6%) were the livers, and one (3.7%) was the heart, and 16 (88.9%) had the PDs corneas captured.

Discussion
The socio-demographic characteristics of PDs reinforce other studies conducted in Brazil, whose profile circumscribes males in the economically active age, single, with low education, in the exercise of professional activity, catholic and living in the metropolitan area [17].

Regarding the donation process, the identification and notification of PD are the initial steps and probably those that bring greater impact on the final number of donor organs and tissues. It is recognized that the low number of notifications is the main cause of the limited rate of transplant donors and the country. The increase in notifications is through awareness of health professionals, courses, and lectures that aim to greater involvement of the multidisciplinary team before the actions of the donation process [11].

It is noted that after the implementation of the POO in 2010, there was a considerable increase in notifications and this action reflected in the number of transplantations. In 2009, the rate of effective donors was 9.0 per million population (ppm), in 2010 went to 9.9 pmp that in 2012 was 12.6 pmp and 14.2 pmp in 2014 [1,18].

After the identification and reporting of PDs, it is necessary to evaluate him. Thus, basic laboratory tests of the protocol should be performed after the first clinical trial, and serology must be requested after consent for donation has been signed. Also, the appropriate clinical and laboratory evaluation is essential for obtaining quality graft, prevention of transmission of infectious or cancer diseases [6]. However, it is noted that tests needed for control and maintenance of major organ functions such as heart, liver, and pancreas, as well as infection control were not performed in most developed countries, which can trigger an unexpected cardiac arrest, hemodynamic instability or infection and interfere with the donation process [14].

Regarding the maintenance of the PD, it is known that the BD can cause multiple deleterious effects on the body, result in cardiovascular instability, metabolic and tissue hypoperfusion. Thus, physiological changes should be detected and treated [6,14]. However, there was a worrying situation regarding such care because this research found for the maintenance of body temperature were not performed properly in most of the PDs.

It was emphasized that temperatures below 34°C could trigger blood vasoconstriction, cardiac arrhythmias, decreased oxygen-binding to all cells, in-
creased blood viscosity and decreased cardiac contractility, as well as the temperature above 35°C, is a prerequisite for the opening of BD protocol [6-7, 15].

As for the diagnosis of BD, the results support up and add up to literature, to reveal that for the follow-up of the donation process, it is imperative to conduct this diagnosis, through the coma because of identification, hypothermia exclusion and the realization of the two neurological evaluations and complementary exam [6-7, 15].

It is also noted that neurological evaluation was not by the legislation in 37.6% because the doctor has not tested all the reflexes needed to evaluate the brain impairment by Resolution Nº 1,480 FCM [7]. This result is reinforced by not confirming the diagnosis of BD for further examination in 7.8% of DPs, even after the completion of the two neurological evaluations.

It is pointed out that to confirm the diagnosis of BD in Brazil, a further examination is essential to carry out even without donor patients. It is stressed that these tests do not confirm the BD, but they complement the diagnosis. Thus, it is a serious conceptual error, in addition to breaching the provisions of the FCM, conducting additional tests to “determine the BD. Therefore, our data in this study contradict the literature stating that when neurological evaluations should be carried out properly in all patients with suspected BD, independent of the completion of additional examination] [6-7].

Regarding the documentation of the BD, a study showed that 90.8% of PDs had the documents with inadequacies. This fact was due to the lack of fulfillment of the death certificate or referral to the STIP shortly after the completion of the final exam, neurological or complementary, performing the examination time annotation was absent [19].

Among the causes of non-effectiveness of transplantation, the family refusal predominated. The family is essential to the donation process successfully happen thus of fundamental importance to assistance provided before and after the development of BD. Since this is an exhausting and remarkable moment, support and clarification should be offered to minimize pain, suffering, and stress experienced by the family [8].

The results are supported by the brazilian registry of transplantations when they stress that unfamiliar authorization is the first cause of not donation in Brazil. These data pointed to the need to inform the population about the donation process and stimulating their consent [1]. In 2014, in Brazil, 9,351 PDs had been identified and notified. Of them, only 2,713 (29.0%) were 14,2pmp donors [18], indexes compatible with the present study.

Thus, the inadequacy in the organ donation process contributes significantly to the low effectiveness, especially at the diagnosis stage of BD, PDs maintenance, family interview and BD documentation and clinical laboratory evaluation PD, a critical to obtaining a quality graft [14,19].

About the implementation of this research, a significant event was the availability of all the families of the PDs and some professionals allowing the observations without any objections. However, not only was gratifying, since the results were worrying, especially as regards the less attention of health professionals to individuals with BD, and it interfered with the quality of care and records in all surveyed. It was also classified as the difficulty of the data collection process as the methodology required the presence of the data collection team every day of the week during the survey period.

From this, it is concluded that the notifications had increased considerably after the implementation of the POO in the study area in 2010, with a positive impact on the number of transplantations. Despite the growth, the results of this study confirmed that several procedures were not carried out properly, such as the laboratory tests necessary for the monitoring of organ function, lack of intensive care needed to maintain the viability of organs and tissues, non-execution of the steps necessary for the diagnosis of BD and documentation of the BD,
and also the most intensive continues to carry out the death certificate or referral to the STIP – Legal Medicine Institute only after cardiac arrest, raising doubts about the concept of BD.

Therefore, the process of donation, by being complex needs one of the good relationships between the multidisciplinary team so that its phases are realized effectively. Thus, each professional assumes the technical and ethical responsibility that full collaboration, paying attention to the patient and family needs.

Thus, besides this study provides important epidemiological information for planning of actions related to the process of organ and tissue donation, it enables reflexive action on this process and the motivation for further studies. Furthermore, this survey reflects the importance of strengthening education geared to the acquisition of knowledge and skills of students in the highly complex care, glimpsing the contribution to the effectiveness of the process of organ and tissue donation.

This study is limited to a local scope context, reflecting the need for research that encompasses other realities to increase knowledge about the aspects that influence the effectiveness of the process of organ and tissue donation.

Conflicts if interest
As authors of this paper, we declare that there are not conflicts of interest.

Abbreviations
- BD: Brain Death
- FCM: Federal Council of Medicine
- NCPODT: Notification Center, Procurement and Organ Donation for Transplantation
- PD: Potential Donors
- POO: Procurement Organization of Organs
- STIP: Scientific-Technical Institute Police

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