







## Epidemiological characterization and causes of non-donation by potential brain-dead organ donors

*Caracterização epidemiológica e causas da não doação por potenciais doadores de órgãos em morte encefálica*

*Caracterización epidemiológica y causas de la no donación de potenciales donantes de órganos en muerte cerebral*

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### ABSTRACT

**Objective:** to analyze the epidemiological characteristics and causes of non-completion of the organ and tissue donation process from potential brain-dead donors. **Method:** cross-sectional study, with secondary data from 2019, obtained from brain death notification forms of patients aged 18 years and over, analyzed descriptively and inferentially, after approval by the ethics committee. **Results:** 231 brain deaths were reported, with a higher incidence of males, average age of 48 years and notifications from public hospitals. In Campo Grande, Mato grosso do Sul, Brazil, there was a greater number of notifications and a shorter time between notification and the first clinical examination (RR: 4.01; CI 2.17-7.41; p<0.001). Among cases of non-donation, 75.8% occurred due to medical contraindication and family refusal. **Conclusion:** there was a predominance of young adults, non-organ donors, whose family's refusal was due to the desire to keep the body intact.

**Descriptors:** Nursing; Brain Death; Donor Selection; Tissue and Organ Procurement.

### RESUMO

**Objetivo:** analisar as características epidemiológicas e causas da não efetivação do processo de doação de órgãos e tecidos de potenciais doadores em morte encefálica. **Método:** estudo transversal, com dados secundários do ano de 2019, obtidos de formulários de notificação de morte encefálica de pacientes com idade igual e superior a 18 anos, analisados descritiva e inferencialmente, após aprovação pelo comitê de ética. **Resultados:** notificadas 231 mortes encefálicas, com maior incidência de pessoas do sexo masculino, idade média de 48 anos e notificações dos hospitais públicos. Na capital do estado, observou-se maior número de notificações e o menor tempo entre a notificação e o primeiro exame clínico (RR: 4,01; IC 2,17-7,41; p<0,001). Entre os casos de não doação, 75,8% ocorreram por contraindicação médica e recusa familiar. **Conclusão:** houve predomínio de adultos jovens, não doadores de órgãos, cuja negativa da família deu-se pela vontade de manter o corpo íntegro.

**Descritores:** Enfermagem; Morte Encefálica; Seleção do Doador; Obtenção de Tecidos e Órgãos.

### RESUMEN

**Objetivo:** analizar las características epidemiológicas y las causas de la no finalización del proceso de donación de órganos y tejidos de potenciales donantes en muerte cerebral. **Método:** estudio transversal, con datos secundarios del año 2019, obtenidos de formularios de notificación de muerte encefálica de pacientes de 18 años y más, analizados de manera descriptiva e inferencial, previa aprobación del comité de ética. **Resultados:** Se reportaron 231 muertes encefálicas, con mayor incidencia de hombres, edad promedio de 48 años y notificaciones de los hospitales públicos. En la capital del estado, hubo mayor número de notificaciones y menor tiempo entre la notificación y el primer examen clínico (RR: 4,01; IC 2,17-7,41; p<0,001). Entre los casos de no donación, el 75,8% se produjo por contraindicación médica y negativa familiar. **Conclusión:** hubo predominio de adultos jóvenes, no donantes de órganos, cuya negativa familiar se debió al deseo de mantener el cuerpo íntegro.

**Descritores:** Enfermería; Muerte Encefálica; Selección de Donante; Obtención de Tejidos y Órganos.

## INTRODUCTION

Organ and tissue transplantation constitutes a therapeutic alternative for many chronic diseases affecting the population, a process that provides an improvement in quality of life and the possibility of resuming daily activities<sup>1</sup>.

Since 1992, Spain has held the world record in absolute and relative values per million population (pmp) for organ donations. In 1989, the rate was less than 15 pmp and progressed to 46.9 pmp in 2017. This achievement can be related to the creation of the National Transplant Organization (*Organización Nacional de Transplante, ONT*) and to the consolidation of the well-known Spanish Transplant Model. Among the many measures adopted are the reinforcement in the role of transplant coordinators and training the teams for interviews with the family and delivering bad news<sup>2</sup>.

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Although it has more modest transplant numbers when comparing to Europe, Brazil gains international recognition for having the largest public system of organ transplants and donations, where nearly 100% of the procedures are carried out using public resources through the Unified Health System (*Sistema Único de Saúde, SUS*)<sup>3</sup>.

In the country, despite the extensive access to the transplant system, there is a significant gap in the scope of effective donations, as evident in national data, with an important discrepancy across regions and states.

The South and Southeast regions of the country stand out for their high rates. In 2019, these areas reached effective donor rates of 36.1 and 19.7 pmp, respectively. These figures are related to the fact that these regions have centers capable of performing all types of transplants<sup>4</sup>.

The Midwest region achieved an effective donor rate of 11.1 pmp, only ahead of the Northern region, which has the lowest rate of effective donors nationwide, with only 3.7 pmp. In 2019, the state of Mato Grosso do Sul surpassed the effective donation rate target of 11.0 pmp, reaching 18.9 donations pmp and securing the seventh position in the country<sup>4</sup>.

At the national level, the actions to reduce the growing imbalance between organ supply and demand point to the need for several improvements that culminate in an increase in donors, primarily related to updates in intensive care knowledge and management by neurological criteria<sup>5</sup>.

In this way, all patients with severe brain injury on mechanical ventilation can be evaluated as potential donors. Swift identification of irreversible neurological evolutions and promptly initiating the Brain Death (BD) protocol can contribute to clinical realization of organ donation<sup>6</sup>.

However, confirmation of the BD diagnosis is required for a patient to become a Potential Donor (PD). In turn, this is defined as complete and irreversible brain function loss, with cortical and brainstem activity cessation<sup>5,7</sup>. It should be characterized and confirmed through clinical and complementary examinations, respecting the time variations specified for each age group<sup>7</sup>.

Decree No. 9,175 from 2017 of the Brazilian Republic Presidency regulates the transplant law and reasserts that autonomy in the decision to donate belongs to the spouses or relatives, following the succession line up to the second degree of kinship for individuals over 18 years old, even in cases where the PD has expressed their will to become a donor during their lifetime<sup>8</sup>.

A PD will only become an Eligible Donor (ED) when there is clinical BD confirmation and authorization from the family for organ and tissue removal<sup>8</sup>. Therefore, the family plays an essential role in the process. Welcoming and interviews are considered the most complex stages of organ and tissue donation. It is the moment when, once BD is confirmed, it becomes necessary to communicate the loss of the loved one and provide diverse information about the process<sup>6,9</sup>.

Good management from the beginning of neurological deterioration and the Organ Procurement Organization (OPO) team meeting with the family member are fundamental for organ and tissue donation to be carried out<sup>9</sup>, as the reduction in the number of EDs is closely related to family refusal, with several reasons leading to this decision<sup>10</sup>. In this context, the success of any donation process requires that potential donors be identified and assessed early in time<sup>5</sup>.

Based on these considerations, the following question arises: Which are the epidemiological and clinical characteristics of patients with BD, and which are the reasons for not carrying out the organ donation process?

The objective of this study was to analyze the epidemiological characteristics and the reasons for not carrying out the organ and tissue donation process in potential donors with BD.

## METHOD

This is a descriptive and analytical study with a quantitative approach and a cross-sectional design, conducted based on secondary data. Structuring of this observational report followed the guidelines set forth in the "Strengthening the Reporting of OBservational studies in Epidemiology (STROBE) – Cross-sectional studies" initiative.

The BD notification forms used were those sent to the Mato Grosso do Sul State Transplant Center (*Central Estadual de Transplante/Mato Grosso do Sul, CET/MS*) in Campo Grande, capital city of the state. Information sent to CET/MS from January 1<sup>st</sup> to December 31<sup>st</sup>, 2019, was collected, and data collection took place from September 2020 to April 2021.

The study population consisted of the PD notifications sent to CET/MS during the period analyzed. Sampling was census-based without the need for sample size calculation; therefore, all forms forwarded to CET/MS for cases where the BD protocols were initiated in 2019 were included in the study. The forms belonging to patients with confirmed BD and aged at least 18 years old were included for analysis. Notification forms with illegible information were excluded, as well as those with inconclusive protocols and those related to minors.

For data collection, an instrument was developed with a checklist according to the printed form standardized by CET/MS and to the donor information form described in the technical regulations set forth by the National Transplant System (*Sistema Nacional do Transplante*, SNT) of the Ministry of Health<sup>6</sup>.

The variables analyzed included the following: sociodemographic profile; city of origin corresponding to the notification and hospital institution; health care plan type; BD causes; process conclusion; reasons for not carrying out the organ donation process; and date and time when the event was communicated to CET/MS, of the initial clinical and complementary examinations, and of the cardiorespiratory arrest. The fields on the forms that were not completed or illegible were considered as “Unknown”.

The data obtained were tabulated in a spreadsheet using Microsoft Office Excel®, and the statistical analysis was performed in the *Statistical Package for Social Sciences* (SPSS) software, version 25.0.

The categorical variables were analyzed descriptively using distributions of absolute and relative frequencies, whereas the continuous variables had central tendency and data dispersion measures calculated.

The Shapiro-Wilk test was used to verify data normality and, in case of non-normal distribution, a non-parametric statistical analysis was applied. The Chi-square test was used to analyze the categorical variables. Relative Risk (RR) calculation with a 95% Confidence Interval (CI) was used to estimate magnitude of the associations. The continuous variables were analyzed using Mann-Whitney's U test and the Kruskal-Wallis test. A 0.05 significance level was adopted for all analyses.

The research protocol was approved by the Committee of Ethics in Research with Human Beings of the teaching institution.

## RESULTS

In 2019, CET/MS received 231 BD notifications, which constituted the sample analyzed in this study. The sociodemographic data of the PDs are described in Table 1.

**Table 1:** Sociodemographic characteristics of the potential organ and tissue donors (n=231). Campo Grande, MS, Brazil, 2019.

Variables	n	%
<b>Gender</b>		
Female	114	49.4
Male	117	50.6
<b>Marital status</b>		
Single	102	44.2
Married	77	33.3
Others	52	22.5
<b>Race</b>		
Brown	132	57.1
White	89	38.5
Black	05	2.2
Indigenous	04	1.8
Unknown	01	0.4
<b>Hospital</b>		
Public	194	84
Public-University	19	8.2
Private	18	7.8
<b>City</b>		
Capital	159	68.8
Inland	72	31.2
<b>Outcome of the notification process</b>		
Donor	56	24.2
Non-donor due to medical contraindication	95	41.1
Non-donor due to family refusal	80	34.7

The patients' mean age was 48 years old ( $\pm 20.1$ ), with prevalence of males, single, mixed race, treated at public hospitals in the state capital, and who concluded the BD notification process as non-donors due to clinical contraindication.

Table 2 details the distribution of the sociodemographic variables according to the outcome of the notification process.

**Table 2:** Sociodemographic characteristics according to conclusion of the notification process (n=231). Campo Grande, MS, Brazil, 2019.

Variables	Donor (n=56)		Non-donor due to medical contraindication (n=95)		Non-donor due to family refusal (n=80)		p-value*
	n	%	n	%	n	%	
<b>Gender</b>							
Female	29	51.8	44	46.3	41	51.2	0.741
Male	27	48.2	51	53.7	39	48.8	
<b>Race/Skin color</b>							
Brown	32	57.1	47	49.4	53	66.3	0.213
White	24	42.9	40	42.1	25	31.3	
Black	0	0.0	04	4.2	01	1.2	
Indigenous	0	0.0	03	3.2	01	1.2	
Unknown	0	0.0	01	1.1	0	0.0	
<b>Hospital</b>							
Public	50	89.3	76	80.0	68	85.0	0.131
Public-University	02	3.6	13	13.7	04	5.0	
Private	04	7.1	06	6.3	08	10.0	
<b>City</b>							
Capital	39	69.7	63	66.3	57	71.2	0.773
Inland	17	30.3	32	33.7	23	28.8	

Note: \*Chi-square test.

The statistical analysis did not show any distinction in the association between the sociodemographic variables and the groups referring to the outcome of the notification process.

The reasons that led to organ and tissue donation denial according to the outcome of the notification process are described in Table 3.

**Table 3:** Reasons that led to not carrying out the donation process due to patients' medical contraindication and family refusal (n=175) Campo Grande, MS, Brazil, 2019.

Reasons for not carrying out the organ and tissue donation process	Contraindication			
	Medical (n=95)		Family refusal (n=80)	
	n	%	n	%
Septic shock	14	14.7	-	-
Outside the age limit	15	15.8	-	-
Cardiac arrest	14	14.7	-	-
Positive serologies	07	7.4	-	-
Hemodynamic instability	08	8.4	-	-
Other reasons	32	33.7	-	-
More than one reason	02	2.1	-	-
Not filled out ("Unknown")	03	3.2	-	-
Unawareness of the potential donor's wish	-	-	11	13.8
Potential donor opposed to donation during their lifetime	-	-	18	22.5
Wish to keep the body intact	-	-	26	32.5
Delay in body release	-	-	08	10.0
More than one reason	-	-	11	13.8
Not filled out ("Unknown")	-	-	06	7.5

Among the BD causes from the total of 231 notifications, vascular reasons were the most prevalent ones, accounting for 60.8% (n=139) of the cases, with 41.0% (n=57) due to unspecified cerebral hemorrhage, followed by hemorrhagic and ischemic strokes at 32.4% (n=45) and 21.6% (n=30), respectively. Traumatic etiologies accounted for 19.9% (n=46) of the BD cases, and hypoxic causes constituted 10.4% (n=24). Tumors were responsible for 2.6% (n=6) and infectious causes for 2.2% (n=5), occurring less frequently. Other unknown reasons and fields in the answers to the forms accounted for 4.8% (n=11) of the sample.

Regarding the time elapsed since notification to CET/MS and the first clinical examination, the interval of one to six hours was the most prevalent, accounting for 59.2% (n=137) of the cases. Although there was also predominance of the one to six-hour interval with 55 (n=23.8%) when analyzing the time between BD and cardiorespiratory arrest (CRA), the forms with missing data and therefore considered as "Unknown" were more predominant at 58.4% (n=135).

The time elapsed between notification to CET/MS and opening of the brain death protocol with performance of the first clinical examination was 4.01 times longer in the hospitals from the capital city when compared to the inland municipalities (CI: 2.17-7.41;  $p < 0.001$ ).

The family's desire to maintain the body intact and the information provided by the relatives that the PDs were opposed to donation during their lifetime were the most prevalent reasons for the "family authorization denial" outcome of the notification process. When analyzing medical contraindication, the "Other reasons" field predominated. Among these cases, 50% were related to confirmed or suspected diagnoses of neoplasms.

## DISCUSSION

Sample's researched participants had a mean age of 48 years old, with prevalence of males and single people. The mean age found in this study was similar to another research conducted with PD data from 2013 to 2018, which observed a predominant age of 42.55 years old<sup>11</sup>.

Regarding the national mean, the result was below what was found in the country and reported in a study conducted by the Ministry of Health between 2009 and 2014, which analyzed the mortality rates according to gender and age group. During this period, an increase in mortality rates was observed among men aged from 50 to 59 years old<sup>12</sup>.

The observed age was lower than the one found in a study conducted in Portugal, which analyzed PD medical records from 2010 to 2015 and verified fluctuations in the mean age from 50.7 to 57.8 over the years, without a linear trend<sup>13</sup>.

As for the BD causes, various diseases can lead to this outcome. However, cardiovascular ones are the main cause of death among adults in the country. A Brazilian study conducted in 2019 pointed out stroke as the second leading cause in this group of diseases. A significant number of deaths due to this problem was found, with a total of 73,290, becoming more prominent after 45 years old<sup>14</sup>. These data corroborate with the findings of this study, where stroke was the leading cause of BD considering the PDs' mean age.

In terms of public and/or private health care networks, it was noticed that public hospitals are responsible for most donors. This can be justified by the fact that Brazil has the world's largest public organ and tissue transplantation system<sup>15</sup>.

The higher rate of donation outcomes in the public health system is justified by the larger and more consolidated SNT structure, which coordinates organ notification, procurement, and donation centers. The SNT is also responsible for integrating state and municipal health departments and providing adequate logistics to operate swiftly throughout the entire notification and donation process in any institution across the country<sup>16,17</sup>.

Regarding the institutions included in the study, a significant difference in the conversion of all 231 BD notifications into eligible donors was observed, with 92.9% concentrated in public institutions, including municipal, state and federal hospitals.

Although university teaching hospitals only accounted for 3.6% of the total notifications, they play a fundamental role as centers for training human resources in the health area and for technological development. They provide society with direct assistance that goes beyond technical updating of professionals throughout the entire network<sup>18</sup>. In this context, it is possible to provide society with duly trained and updated professionals on the study topic, contributing to the public health system efforts to achieve efficiency standards, as observed in a study conducted in Spain between two Spanish health care centers, one of which was a university hospital. The actual donation rate of 101 confirmed BDs did not differ between the hospitals, with a 33% rate for both institutions<sup>19</sup>.

The training and experience of the professionals involved in this type of assistance are crucial criteria for a positive outcome, a fact implemented in the Spanish model<sup>2</sup>. Therefore, it is important for teaching and research institutions to disseminate knowledge about the entire organ and tissue donation process and to train health professionals to be more critical, reflective and effective in their care practices, especially in this line of work<sup>19</sup>.

Regarding the organ and tissue donation management process, it was observed that notification to CET/MS and the first clinical examination mostly took place within six hours. The significance of early notifying the PD is stated in the current national legislation, requiring urgent and mandatory notification<sup>7,8</sup>.

Organization, coordination and regulation of donation and transplantation activities along with the SNT must be carried out promptly to ensure premature clinical care for the PDs, aiming at hemodynamic stabilization. These actions exert a relevant impact on preserving quality of the organs and increasing the chances of effective donations, as well as organ and tissue supply for transplantation<sup>20</sup>.

The difficulty related to the notifications from the farthest regions from the state capital city can be explained by the extremely widespread distribution of the municipalities. The state of Mato Grosso do Sul has a large area and currently has two OPOs to serve the entire territory. In addition to that, this challenge can worsen due to lower availability of resources related to necessary devices and still insufficient and inexperienced teams, which impacts the dynamics and logistics of the entire organ and tissue donation process<sup>20,21</sup>.

The time elapsed between BD confirmation and CRA corresponds to the period during which the PD remained under the care of the Intensive Care Unit (ICU) multiprofessional team. In other words, the PD health status is maintained to ensure stable organic functions and organs suitable for transplantation<sup>22,23</sup>. In this study, there was absence of records regarding the time elapsed between BD confirmation and CRA in nearly 60% of the form analyzed.

Regarding the clinical aspect of maintaining the PD health status, it is asserted that time is the determining factor for success and that it exerts a direct interference on quality of the grafts and, consequently, on performance of the organ and tissue transplantation, as well as the institutionally evaluation of this process<sup>21,23</sup>. This can be associated with the difficulty faced by medical professionals in determining the legal time of death, a result found in a study aimed at assessing the knowledge of 90 physicians working in ICUs about BD<sup>24</sup>. This is a relevant piece of information, as successful donation programs fundamentally depend on the timely identification, referral and evaluation of all potential donors<sup>25</sup>.

In this study, more than 75% of the cases were defined as non-donors, and it was observed that medical contraindication outweighed family refusal. Among the medical clinical records, those that evolved to CRA, inconclusive protocols and other contraindications were identified, especially neoplasms, which represented high numbers.

It is noted that cancer is among the top four causes of death before 70 years old worldwide. Its incidence and mortality rates are on the rise, with several factors contributing to this increase, such as aging and the prevalence of risk factors, especially those associated with life habits<sup>26</sup>.

The PD family refusal percentage found is similar to the national data. In 2020, the Brazilian Association of Organ Transplants (*Associação Brasileira de Transplantes de Órgãos*, ABTO) reported that 69% of the PDs did not result in donations, with 37% of them due to family refusal<sup>27</sup>. Such data reassert the family refusal high rates; the scientific literature points out that this situation may reflect lack of understanding among family members about the BD process, which, in turn, questions death in the presence of heartbeats and breathing, even with clinical support<sup>28</sup>.

When information about BD is given to a family member, a path permeated by dilemmas, fears, anxieties and doubts is initiated, compounded by limited or nonexistent knowledge about brain failure, as well as unawareness of the potential donor's wishes<sup>29</sup>.

In this context, it is important to separate the communication of death from the potential organ and tissue donation, which, in turn, should never be presented to the family until they understand and accept the unavoidability of their loss<sup>30</sup>.

Therefore, requesting organ and tissue donation from a deceased person is not an easy task for professionals, let alone for the family. Among the factors contributing to the difficulty in communication is the professionals' unpreparedness to deliver bad news and the varied social understandings that permeate this field of health treatments<sup>29</sup>.

Many factors should be considered during the interview, such as environment, shift, schooling level and degree of kinship. A study conducted in the state of Rio Grande do Sul observed that interviews conducted during daytime hours were more favorable for acceptance, as well as families with higher schooling levels and lineal or collateral degrees of kinship<sup>31</sup>.

Also, regarding family refusal, international studies emphasize that presence of the family in the ICU during the BD confirmation protocol assists in understanding the process<sup>32</sup>.

When considering the complexity inherent to the procedure, which goes beyond technical aspects, it is important for public policies aimed at training teams not to be only restricted to the diagnosis methods and organ and tissue donation but also to guide these professionals to understand the meanings of life or death for the individual and their impact on the family approach<sup>33</sup>.

In the sensitive performance of the health professionals assisting the family in accepting BD and understanding the possibility and benefits of organ and tissue donation, the Nursing team role stands out. This role goes beyond technical and scientific knowledge because it involves the PD family and the potential donation<sup>34</sup>. In the context where

Nursing professionals are present from the first hospitalization day to the most critical phase and to the end of life, the role of these professionals can exert a positive impact on this process that begins with welcoming, as well as sensitive and qualified listening to the family members.

Establishing closer relationships between Nursing professionals and the family can generate trust and, as a result, the information provided by the health team tends to be better understood by the family<sup>26</sup>.

In this sense, nurses play a central role in managing and providing assistance to PDs and their family. With knowledge, skills and experience, these professionals take on most of the organization of the activities that emerge at every stage of the donation process, ensuring a safe and high-quality process<sup>35</sup>.

### Study limitations

The topic is highly relevant. However, there is a limitation regarding the data time frame, restricted to 2019, as data collection took place during a pandemic period with difficulty accessing the form filing locations due to biosafety measures. In addition to that, the use of data from secondary sources was also considered a limitation, as low-quality records and incomplete information were found, which were processed to contribute to the epidemiological profile of the study.

### CONCLUSION

It was possible to conclude that the sociodemographic profile of PDs in the state of MS during 2019 did not influence the performance of organ and tissue donation procedures. The patients' mean age was 48 years old, with prevalence of males, single people and mixed race, treated at public hospitals in the state capital, and who concluded the BD notification process as non-donors due to medical contraindication. When considering the care locus, the state capital presented a shorter time interval between the notification and the first clinical examination.

Regarding the outcome of this process, a high non-performance rate was observed within a single year, encompassing approximately 80% of the cases, with prominence of family refusal. These findings suggest that implementing new and current policy approaches to this theme might lead to improvements.

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Conceptualization, G.F. P and M.C.S.; methodology, G.F. P and M.C.S.; software, G.F. P and M.C.S.; validation, G.F. P and M.C.S.; formal analysis, G.F.P.; M.C.S. and C.M.P.; investigation, G.F.P. and M.C.S.; resources, M.A.F.J.; data curation, G.F.P.; M.C.S. and C.M.P manuscript writing, G.F.P.; M.C.S.; C.M.P.; M.A.F.J.; C.R.H. and M.L.I.; manuscript review and editing, G.F.P.; M.C.S.; C.M.P.; M.A.F.J.; C.R.H. and M.L.I.; visualization, G.F.P.; M.C.S. and C.M.P.; supervision, G.F.P.; M.C.S.; C.M.P. and M.A.F.J.; project administration G.F.P.; M.C.S.; C.M.P. and M.A.F.J.; financial support, M.A.F.J. All authors have read and agreed to the published version of the manuscript.