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ORIGINAL ARTICLE

ANALYSIS OF THE FACTORS THAT INFLUENCE THE CORNEA DONATION PROCESS

ANÁLISE DOS FATORES QUE INFLUENCIAM O PROCESSO DE DOAÇÃO DE CÓRNEAS ANÁLISIS DE LOS FACTORES QUE INFLUYEN EN EL PROCESO DE DONACIÓN DE CÓRNEAS

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ABSTRACT

Objective: to analyze the factors that influence the process of donating corneas. **Method:** a descriptive, cross-sectional, quantitative study using secondary data collected in the death books, patient records and records of the Notification, Collection and Distribution Center of Organs of Zona da Mata. Variables analyzed: potential donor, family refusal, medical contraindications, logistical or structural problems and donation of corneas. The data collected were processed using the SPSS program, version 14.0 for Windows, and analyzed by descriptive statistics tools as absolute and relative frequencies. **Results:** 863 deaths were recorded. 16% of the deaths were not reported by the nurse to the Notification Center. Of the deaths reported, 21.5% were identified as potential donors and, of these, 37.2% did not donate due to family refusal and 43.6% due to logistical or structural institutional problems. Only 25% of the corneas were transplanted. **Conclusion:** several factors influence the process of donating corneas, generating losses that will impact the final number of transplants. **Descriptors:** Cornea; Corneal Transplantation; Nursing.

RESUMO

Objetivo: analisar os fatores que influenciam o processo de doação de córneas. **Método:** estudo descritivo, transversal, de abordagem quantitativa, que utilizou dados secundários coletados nos livros de óbitos, prontuários dos pacientes e nos registros da Central de Notificação, Captação e Distribuição de Órgãos da Zona da Mata. Variáveis analisadas: potencial doador, recusa familiar, contraindicações médicas, problemas logísticos ou estruturais e doação de córneas. Os dados coletados foram processados utilizando-se o programa SPSS, versão 14.0 para Windows, e analisados por ferramentas de estatística descritiva como frequências absolutas e relativas. **Resultados:** foram registrados 863 óbitos. 16% dos óbitos não foram notificados pelo enfermeiro à Central de Notificação. Dos óbitos devidamente notificados, 21,5% foram identificados como potenciais doadores e, destes, 37,2% não efetivaram a doação devido à recusa familiar e 43,6% devido a problemas logísticos ou estruturais institucionais. Apenas 25% das córneas captadas foram transplantadas. **Conclusão:** diversos fatores influenciam no processo de doação de córneas gerando perdas que impactarão no número final de transplantes. **Descritores:** Córnea; Transplante de Córnea; Enfermagem.

RESUMEN

Objetivo: analizar los factores que influyen el proceso de donación de córneas. **Método:** estudio descriptivo, transversal, de abordaje cuantitativo, que utilizó datos secundarios recogidos en los libros de óbitos, registros médicos de pacientes y en los registros del centro de notificación, captación y distribución de órganos de la Zona da Mata. Variables analizadas: donador potencial, rechazo familiar, contraindicaciones médicas, problemas logísticos o estructurales y donación de córneas. Los datos recogidos fueron procesados utilizando el programa SPSS, versión 14.0 para Windows y analizados por herramientas de estadística descriptiva como frecuencias absolutas y relativas. **Resultados:** se registraron 863 muertes. 16% de las muertes no fueron notificados por el enfermero al Centro de Notificación. De las muertes debidamente notificadas, 21,5% se han identificados como posibles donantes, y de éstos, 37.2% no efectuaron la donación debido al rechazo familiar y 43,6% debido a problemas logísticos o estructurales. Sólo 25% de córneas recogidas fueron trasplantadas. **Conclusión:** varios factores influyen en el proceso de donación de córneas, generando pérdidas que impactarán en el número de trasplantes. **Descriptores:** Córnea; Trasplante de Córnea; Enfermería.

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INTRODUCTION

The technological advance in the field of health sciences, specifically in the area of organ and tissue transplantation, has brought hope to many people with chronic diseases, who aim to recover a healthy lifestyle. In addition to these advances, society is faced with ethical and legal discussions involving donation and human rights in an attempt to increase the number of transplants.

In Brazil, the Unified Health System (UHS) is responsible for coordinating the transplantation system, by adopting the National Policy on Organ and Tissue Transplantation, which is based on Legislation (Law 9,434 / 1997 and Law 10,211 / 2001). Donation free of charge, beneficence towards recipients, and non-maleficence toward living donors.¹

The process of donating organs and tissues involves society, public agencies and health professionals. This complex system (society - public bodies - health professionals) needs to function harmoniously, so that there is donation, capture and subsequent organ transplantation.

One of the most accomplished transplants in Brazil is the cornea, which, since 1998, has been performed in greater numbers due to the expansion of the age range of the donor population, the better selection of donor tissue, the new operative techniques that allow surgery in situations considered inoperable until ten years ago and to the growing awareness of the population.²

Another fact that contributed to the growing number of this type of transplantation was the appearance and performance of the new eye banks in the country and the National Transplant System (NTS), through the State Centers for Notification, Fundraising and Distribution of Organs (CNCDO's), allied to interest and political support.² In addition, the creation of the Intra Hospital Organ Donation and Transplant Tissue Commissions (CIHDOTT), whose main purpose is to improve the organ procurement process, the identification of the potential donors and the family approach, favoring the articulation of the hospital with the respective CNCDO, which, in the end, will enable a qualitative and quantitative increase in organ recruitment.³

It is known that visual impairment, besides generating important social consequences, also has an impact on the quality of life of the individual. Corneal transplantation is an alternative capable of providing the visual

recovery of an individual with visual impairment caused by corneal pathologies and, thus, reinserting it into society.⁴

The corneal transplantation, as well as the others, is being performed in a much smaller number than the desired one, due to obstacles such as the lack of information of the population and the professionals involved in this process, the wrong medical contraindication, besides the refusal of consent of the donation by the family.^{1,5-7} Studies confirm that, even when the donation occurs, a large part of the corneas is not carried out in transplants.⁸

According to Ordinance n. 1.262, of June 16, 2006, art. 5, the possibility of capturing corneas for transplantation is directly related to the number of deaths in the institution. It is considered appropriate to interview the relatives of deceased patients in the hospital, offering the possibility of corneal donation, guaranteeing the donation to be completed within a maximum period of six hours after finding the death in 100% of the cases, except for the defined medical contraindications by CNCDO and Linked Eye Bank; and obtain a minimum of 20% of effective corneal uptake in relation to the interviewed cases.⁹

The main causes of donation of organs and tissues for transplantation are determined by family members' refusal, medical contraindication and the existence of logistical or structural problems.⁹

In view of the exposed situation, which shows a disproportion between the number of potential donors and the number of actual donors for corneal transplantation, the following guiding questions were raised: Are all deaths reported to the CNCDO? What is the frequency of family refusals, medical contraindications, and structural and logistic problems that occur in the corneal donation process? Are corneas taken transplanted? What are the reasons for discarding corneas?

Studies that address these issues are scarce, especially, when aspects such as family refusal, medical contraindications and structural and logistic problems are considered as main obstacles in the effectiveness of the process of donation of corneas.

OBJECTIVE

- To analyze the factors that influence the process of donating corneas.

MÉTHOD

A cross - sectional, descriptive, quantitative approach using secondary data

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collected in the death books, patient records and CNCDO 's records from Zona da Mata. We used a road map that guided the data collection defined by the following steps:

1. Tracing of all deaths occurred in two hospitals in Juiz de Fora from January 1st to December 31st of the year 2010.

2. After confirming the deaths, data were investigated in the death register of patients' institutions and medical records in order to identify potential donors of corneas.

3. It was verified if all the deaths reported were notified to the CNCDO of Zona da Mata of Juiz de Fora and whether or not this notification resulted in donation of the corneas. In cases where the donation was not effected, the justification of the cause for this non-donation was sought. For the cases in which the cornea was collected, the final destination of the organ (transplantation or loss) was analyzed.

The research scenario involved a Public Hospital and a Private Hospital of Juiz de Fora selected for offering a large number of vacancies for hospitalizations in the most diverse specialties (clinical, surgical and intensive care), attending patients in different clinical conditions, which could either evolve to Improvement in their health condition, receiving hospital discharge, and worsening of their condition, culminating in death. Also included in the scenario are the CNCDO of Zona da Mata de Juiz de Fora and the Ocular Tissue Bank of Juiz de Fora (BTOC-JF). It should be noted that, during the study period, both hospital institutions were in the process of implanting the Intra Hospital Organ Donation and Transplant Tissue Commission (CIHDOTT).

The data collected were processed using the Statistical Package for the Social Sciences (SPSS), version 14.0 for Windows, and analyzed by descriptive statistics tools such as absolute and relative frequencies.

Variables related to the process of donation of corneas defined by seven groups were analyzed, considering Administrative Rule No. 1,262, dated June 16, 2006,⁹ and the protocol developed by the Hospital Foundation of the State of Minas Gerais (FHEMIG) in 2008¹⁰, revised in 2010, which Are in compliance with the Resolution of the Collegiate Board of Directors (RDC) nº 67, of September 30, 2008¹¹:

1. Variables related to sociodemographic characteristics: institution where the death, sex and age of the patient occurred. The age range was considered adequate for donation of eyeballs being greater than two years and

less than 80 years of age; the interval was defined as a lower age (<) than two years, age between two years and 80 years, greater age (>) than 80 years;

2. Variables related to the potential donor: cases that did not present the medical contraindications and other relative contraindications defined by the CNCDO of Zona da Mata of Juiz de Fora were considered as potential donors;

3. Variables related to family refusal: ignorance of the donor's desire, donor contrary to donation while in life, indecisive relatives, family members desire the whole body, family members dissatisfied with care, fear of delay in releasing the body, religious convictions and others;

4. Variables related to medical contraindications: patients with HIV, HTLV, hepatitis B, hepatitis C, hepatitis C, sepsis or septic shock, out of age (<or = two years and > or = 80 years), with neoplasia with metastasis, tumor Cerebral or leukemia, with ocular lesion, contraindication of ocular history, retinoblastoma, malignant tumors of the anterior segment of the eye or adenocarcinoma, keratoconus or ceratoglobus in the eye and others;

5. Variables related to logistical or structural problems: family not located in a timely manner, structural deficiency in hospital (death is not notified by the institution to the CNCDO in an adequate time - greater or equal to six hours after death), structural deficiency or Logistics of CNCDO Of the Zona da Mata de Juiz de Fora (situations that prevent the capture of eyeballs, such as, the absence of staff available for capture) and others;

6. Variables related to the donation of corneas: transplantation or discard of the donated cornea. The variables related to the discard of corneas were categorized as follows: HIV serology, reactive serology for Hepatitis B, reactive serology for Hepatitis C, reactive serology for HTLV, the two corneas are unsuitable for transplantation due to poor quality of the left cornea is inadequate for transplantation due to poor quality and the right cornea is unsuitable for transplantation due to poor quality.

The project was approved by the Human Research Ethics Committee of the Federal University of Juiz de Fora, under favorable opinion, CAAE 0154.0.180.000-11.

RESULTS

There were 863 deaths and, of these, 73.1% occurred in the Private Hospital and 26.9%, in the Public Hospital. 53.1% were male, 0.6% were younger than two years old, 69.1% were between two and 80 years old, and 30.3% were older than 80 years. There was a loss of 0.6% of the age records, because they were not filled in the death register, and it was not possible to identify the patient and the medical record due to the illegibility of the letter of the filling.

All deaths should have been reported by the hospitals to CNCDO, a function assigned to nurses in both institutions. The nurse notifies the death to CNCDO that, they immediately, send a team to the hospital to perform the family approach, request authorization for

donation and to get the donor's corneas. However, 16.0% of the deaths were not reported, and of these, 39.2% were cornea donor potentials that were no longer addressed by the CNCDO, making the donation process unfeasible. There is no justification for the death not to be notified to CNCDO, since, in the institutions where the study was carried out, the notification was mandatory.

Of the deaths that were duly notified to CNCDO, 21.5% were potential donors and, 37.2% did not donate due to family refusal and 43.6% due to logistical or structural problems. 78.5% of the cases were not considered as potential donors because they presented some medical contraindication for donating corneas. Figure 1 shows a synthesis of the corneal donation process focusing on the losses occurred during the donation process.

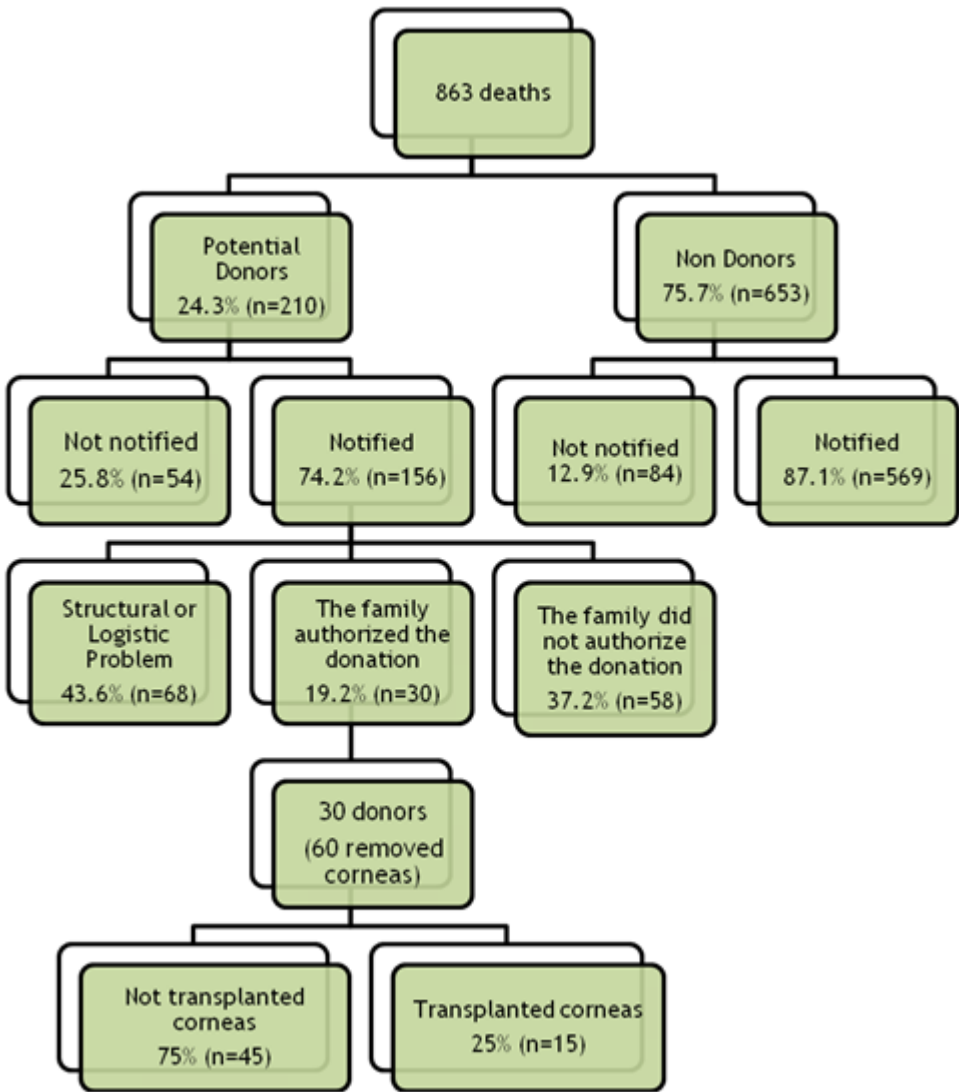


Figure 1. Distribution of losses during the corneal donation process. Juiz de Fora (MG), Brazil, 2015.

Regarding the medical contraindications that prevented donation, 1.7% had HIV, 0.5% had hepatitis B, 1.2% had hepatitis C, 39.5% had sepsis or (<or = two years and> or = 80 years), 2.8% had metastatic neoplasms, a brain tumor or leukemia, 0.3% Had ocular lesions or had contraindications due to ocular history, retinoblastoma, malignant tumors of the anterior ocular segment or adenocarcinoma, keratoconus or ceratoglobus

in the eye, and 16.8% had other causes. There was no contraindication for HTLV.

With regard to family refusals for donating corneas, most did not specify the reason (67.1%). Of the justifications given by the families, it is worth noting: donor contrary to the donation in life (8.6%), undecided relatives (12.1%), relatives who wish to maintain the integrity of the body (5.2%), fear of delayed release of the body (3.5%) and who

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do not know the donor's desire (3.5%). There were no relatives who justified their refusal due to religious convictions and discontent with the care received by the institution.

Regarding logistical or structural problems that impeded donation, the most frequent problem (52.8%) was related to hospital structural deficiency, which means that a high percentage of potential donor deaths were not reported in adequate time (time > or = six hours after death-) so that the CNCDO could carry out the donation. Another problem highlighted is the fact that the family was not located in a timely manner (37.6%) so that the donation could be carried out. And, also, the structural deficiency of the CNCDO / Zona da Mata corresponded to 8.0% of the problems, being almost always justified by the lack of available equipment for capturing corneas. 1.6% of logistical or structural problems that prevented donation were not justified.

It is worth noting that a percentage of the actual number of donors / total number of interviewees who authorized and who did not authorize the donation x 100 was obtained.

At the end, corneas of only 30 donors were found, corresponding to 19.2% of the total number of potential donors reported and 3.4% of the total population surveyed. Of the 30 donors of corneas, 76.6% were from the Public Hospital and 23.4% from the Private Hospital, and the majority (73.3%) were male.

When considering that each donor can donate two corneas, of the 60 corneas captured, only 25.0% were transplanted (16.7% in the right eyeball and 8.3% in the left eyeball).

Regarding the reason for the discard of corneas, 2.2% of the corneas were discarded due to positive serology for HIV, 4.4% due to positive serology for hepatitis B, 2.2% due to positive serology for Hepatitis C, 35.6% of right corneas and 46.8% of left corneas due to poor quality of these tissues. There was no corneal discard for HTLV-positive serology.

DISCUSSION

There was a great loss of potential donors throughout the process of donating corneas. The first major loss occurred when the nurse responsible for reporting the death at these institutions stopped performing this function, rendering the donation process unfeasible. It is believed that, the more relatives of deceased patients are interviewed, the greater the possibility of donations, abstractions and transplants of corneas.⁹ Even with these losses, it was observed that the percentage of effective collection of the cases

interviewed (34.1%) was higher than that recommended by Administrative Rule no. 1,262, of June 16, 2006.⁹

Another situation that led to the loss of potential donors and also related to the attribution of the nurse in notifying the death to CNCDO is the fact that this professional was not able to report the death in a timely manner (less than six hours after death) to that the CNCDO could make the complete approach to the donation process.

These problems raise the following questions: Why are the nurses of the institutions under study failing to fulfill their role by not notifying the deaths to the CNCDO? Why nurses cannot report the death in a timely manner (less than six hours). Such inquiries would need to be investigated in another study so that this problem could be solved.

Given this, it is accepted that having an active CIHDOTT would influence the resolution of problems related to notification of deaths and other structural and logistical problems. It is worth remembering that the hospitals where the study was carried out had a weak CIHDOTT, in the initial process of implantation.

In spite of being a new reality, the CIHDOTTs were created 14 years ago¹², based on the Spanish model³, with the main objective of increasing organ procurement and supporting the CNCDO activities. The obligation of its existence and its effective functioning is defined by art. 1 of Administrative Rule MH/ GM n. 1752, dated September 23, 2005,¹³ which establishes that all public, private and philanthropic hospitals, with more than 80 beds, must have CIHDOTT, a situation pertinent to the hospitals where the research was carried out.

Although there are no concrete data on the registration of CIHDOTTs in the national territory, it is clear that they are more present and active in the capitals, because they are places where there are more transplants being carried out.¹⁴ What is suggested is that the registration of the CIHDOTTs in hospitals still remains sluggish, mainly, because there is no supervision to ensure its existence.

Another great loss observed in the process of corneal donation was the presence of a medical contraindication found in the cause of death, with emphasis on the presence of sepsis or septic shock and deaths outside the age range for donation (<or = two years and> or = To 80 years). A prospective study was carried out in 65 hospitals from all regions of

Brazil, in 2003, in order to better understand the epidemiology of sepsis in Brazil and it was found that mortality in sepsis, severe sepsis and septic shock was 16.7 %, 34.4% and 65.3%, respectively, thus evidencing a high mortality due to sepsis in our country.¹⁵ In addition, the current profile of population aging in Brazil has been undergoing a process of increasing longevity and, according to the census conducted in 2010, by the Brazilian Institute of Geography and Statistics (IBGE), life expectancy at birth for the population of both The sexes averaged 73.76 years (73 years nine months and three days).¹⁶ These data corroborate with the findings of the research.

There was also a great loss in the process of corneal uptake related to donors' family refusals, a fact also pointed out by other studies as a serious problem and that prevents the growth in the number of transplants.¹⁷⁻¹⁸ Rech and Rodrigues Filho point out that the main reason for non-uptake of organs from potential donors is the refusal of the family member. In the United States, approximately half of the families approached said no to the donation. In Brazil, the refusal rate reaches 70% in the less developed regions of the country. On the other hand, studies show that approximately 65% of people are in favor of donation, a percentage discordant from current conversion rates.¹⁹

This study pointed out that the majority of donors' relatives did not specify the reasons that made them choose to refuse donation, but it is believed that one of the main reasons that influenced families to opt for non-donation is that they do not know the desire of their relative on the subject.¹⁹ Sadly, most people do not make this decision in life, and even those who do not end up informing their families.¹⁹

Nurses play an important role in sensitizing the family of potential donors on the issue of donation, since family refusal is one of the factors that most influence the scarcity of organs and tissues. The decision of the family of the potential donor, will make the death of their loved one a chance for a new life for other people.²⁰

A study conducted in Ohio in the United States, aimed to test the effect of an educational intervention conducted with the coordinators of Organ Procurement Organizations. The purpose of the intervention was for the coordinators to develop technical communication skills to ensure an adequate approach to the family of the potential organ donor and, thereby, increase consent rates. It was verified that the family consent for donation increased

significantly after the educational intervention (from 46.3% to 55.5%). This study demonstrates the importance of performing this type of training with the professionals involved in the donation process, especially the nurse, who is responsible for the family approach.²¹

It is also highlighted, as a factor of influence in the donation process, the rate of discard of corneas captured (75%), which is considered high when compared to the study by Michelon et al. (2009), whose overall discard rate was 29% .⁴

The main cause of corneal discard in this study was due to poor tissue quality. The 1st Report of Evaluation of the production data of BTOCs carried out in 2009, in Brazil, by the National Agency of Sanitary Surveillance (ANVISA), also highlighted, as the main reason for discarding the corneas is the improper quality of the tissue (33.7%). The other reasons were: reactive serology for hepatitis B (32.9%), validity of the cornea (16.5%), unjustified discards (6.6%), reactive serology for hepatitis C (5.4%), , Clinical contraindication for transplantation (2.3%), HIV reactive serology (2%) and corneal contamination (0.6%).

The data show that there is more discarding for poor quality of corneas than for reactive serologies. This may be associated with the age of the donor, since younger donors had their corneas transplanted, while the corneas of the older donors were discarded.

Further research has also found that corneas from younger donors have significantly better scores than those from older donors⁽²³⁾ and, among factors inherent to the donor, the age group over 60 years predisposed the poorer anatomical quality of the corneas.²⁴

The Cornea Donor Study demonstrated that the cornea should not be considered inadequate for transplantation when only the advanced age of the donor is analyzed, and its tissue quality and endothelial count should also be considered. In addition, factors such as the donor's cause of death and the length of stay of the donor cornea in the preservation media also influence its quality for transplantation purposes.²⁴ However, the only factor analyzed in this study was the donor's age, which may have negatively influenced the quality of the cornea captured, because, the greater the donor's age, the worse the corneal anatomical condition, although there are studies that challenge this fact.²⁴ Thus, further studies should be carried out to determine which factors should be

considered to improve the quality of transplanted eye tissue.

CONCLUSION

There was a disproportion between the number of potential donors and the number of actual donors for corneal transplantation, since much was lost throughout the donation process.

The nurse plays a fundamental role in this context, being the starting point for the process to begin, through simple notification of death. It was verified, in this research, that the underreporting was a great obstacle for corneal uptake to take place. In addition, there were relatives who refused to make the donation without even specifying the reason. Therefore, it is necessary to promote educational measures such as organ and tissue donation campaigns, involving social, governmental and non-governmental organizations, as well as private initiative, in order to generate integrated actions capable of demystifying the donation process and positively impact the final number of transplants performed.

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