CAPTAÇÃO DE CÓRNEAS E A ESTATÍSTICA DE NOTIFICAÇÕES

CORNEAL HARVESTING AND NOTIFICATION STATISTICS

ESTADÍSTICAS DE RECOLECCIÓN Y NOTIFICACIÓN DE CÓRNEAS

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RESUMO

A captação de córneas no Brasil é regulamentada por leis e normas que garantem a ética e a segurança do processo de doação, em conformidade com a Lei nº 9.434/1997 e a Resolução nº 1.480/97 do Conselho Federal de Medicina. Este estudo teve como objetivo mapear as notificações e causas de exclusão para obtenção de córnea em um banco de olhos de uma cidade no sul do Estado do Rio de Janeiro no ano de 2023. Para isso, utilizou-se uma metodologia quantitativa, analisando dados estatísticos de 1.600 notificações de óbito utilizando o software Excel® para organização destes dados. Os resultados revelaram que as exclusões foram predominantemente por faixa etária, 455

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casos e contraindicações clínicas, 422 casos, com a sepse como a terceira maior causa de exclusão, totalizando 369 registros. Os dados indicam que a conscientização sobre a doação de tecido ocular e a resistência familiar são fatores críticos que afetam as taxas de captação. Conclui-se que há uma necessidade pública urgente de campanhas educativas e políticas mais eficazes para melhorar a doação de córneas no país. O aprimoramento do treinamento dos enfermeiros e a capacitação contínua dos outros profissionais podem aumentar a elegibilidade de potenciais doadores, contribuindo assim para a melhoria dos índices de captação.

Palavras-chave: Córnea. Obtenção de Tecidos. Enfermeiros. Dados Estatísticos.

ABSTRACT

The collection of corneas in Brazil is regulated by laws and standards that ensure the ethics and safety of the donation process, in accordance with Law No. 9.434/1997 and Resolution No. 1.480/97 from the Federal Council of Medicine. This study aimed to map the notifications and reasons for exclusion in obtaining corneas from an eye bank in a city in the southern part of the State of Rio de Janeiro in 2023. A quantitative methodology was employed, analyzing statistical data from 1,600 death notifications using Excel® for data organization. The results revealed that exclusions were predominantly by age group, with 455 cases, and clinical contraindications, with 422 cases, with sepsis being the third leading cause of exclusion, totaling 369 records. The data indicate that awareness of ocular tissue donation and family resistance are critical factors affecting collection rates. It concludes that there is an urgent public need for educational campaigns and more effective policies to improve cornea donation in the country. Enhancing nurse training and ongoing education for other professionals can increase the eligibility of potential donors, thereby contributing to improved collection rates.

Keywords: Cornea. Tissue Procurement. Nurses. Statistical Data.

RESUMEN

La recolección de córneas en Brasil está regulada por leyes y normas que garantizan la ética y la seguridad del proceso de donación, de acuerdo con la Ley nº 9.434/1997 y la Resolución nº 1.480/97 del Consejo Federal de Medicina. Este estudio tuvo como objetivo mapear las notificaciones y los motivos de exclusión en la obtención de córneas de un banco de ojos de una ciudad de la zona sur del Estado de Río de Janeiro en 2023. Se empleó una metodología cuantitativa, analizando datos estadísticos de 1.600 notificaciones de defunción utilizando Excel® para la organización de los datos. Los resultados revelaron que las exclusiones fueron predominantemente por grupo etario, con 455 casos, y contraindicaciones clínicas, con 422 casos, siendo la sepsis la tercera causa de exclusión, totalizando 369 registros. Los datos indican que la conciencia sobre la donación de tejido ocular y la resistencia familiar son factores críticos que afectan las tasas de recolección. Se concluye que existe una necesidad pública urgente de campañas educativas y políticas más efectivas para mejorar la donación de córneas en el país. Mejorar la formación de enfermeras y la educación continua de otros profesionales puede aumentar la elegibilidad de posibles donantes, contribuyendo así a mejorar las tasas de recolección.

Palabras clave: Córnea. Adquisición de Tejidos. Enfermeras. Datos Estadísticos.

INTRODUCTION

Cornea harvesting in Brazil is supported by a set of laws and standards that ensure ethics and safety in the donation process (Ribeiro, 2020). Law No. 9,434/1997, known as the Transplant Law, establishes the fundamental principles for the removal and transplantation of organs, tissues and parts of the human body (Cardoso; Júnior, 2022). In addition, Resolution No. 1,480/97 of the Federal Council of Medicine (CFM), details the specific procedures for the donation of ocular tissues, including corneas (Da Silva *et al*., 2023).

Corneal harvesting is carried out by specialized teams, usually linked to hospitals and eye banks, who follow strict protocols to ensure the viability of the tissue and the safety of the recipients (Emerick, 2022). The recruitment process involves the identification of potential donors, clinical and laboratory evaluation to ensure the absence of contraindications, and, finally, the removal and preservation of the corneas in ideal conditions (Da Silva *et al*., 2020).

The criteria for the election of potential donors include factors such as the age of the donor, absence of infectious or systemic diseases that may compromise the tissue, and prior authorization for donation, which can be manifested by the individual himself or by his family. The selection is made carefully to maximize the chances of success in transplants.

Corneal harvesting is conducted by qualified professionals, trained and qualified in techniques for removing and preserving ocular tissues (Lysakowski *et al*., 2023). These professionals work closely with the eye banks, which are responsible for the screening, storage, and distribution of corneas.

Brazil has a network of corneal banks strategically distributed across several regions, which facilitates the coverage and speed of tissue distribution. According to recent data, there are dozens of eye banks in operation in the country, located in states such as São Paulo, Rio de Janeiro, Minas Gerais, among others (ANVISA, 2020). These banks are essential to ensure that the harvested corneas are efficiently made available to recipients throughout the national territory, contributing to the reduction of the waiting list for transplants and the improvement of the quality of life of thousands of patients.

The lack of interest, awareness, myths, beliefs, and family denial (Magalhães *et al*., 2020) about organ donation by the population may be one of the factors that make organ donation, donation, and transplantation in the country still a factor with low statistical rates compared to other countries (Rodrigues *et al.*, 2023).

It is extremely important to map and identify the indices related to corneal harvesting and transplantation. Thus, we defined as the object of study the notification statistics of a

bank of corneal harvesting for transplants.

The following guiding questions were: How many notifications for corneal harvesting were attended to and excluded in 2023? What are the exclusion reasons for corneal transplants?

The objective was to identify the total number of notifications attended and excluded during the year 2023 for corneal transplantation; list the main death notifications and causes of exclusion for corneal transplants; prepare an educational folder on awareness of the importance of donation.

This study is justified due to the importance of raising awareness of the population in relation to organ donation, as there is still a lot of resistance to dealing with the subject.

The relevance of this study is due to the possibility of increasing the population's knowledge regarding cornea donation, and with this it is believed in greater awareness of the importance of this noble act.

METHODOLOGY

The study consists of a quantitative, descriptive, exploratory research. Quantitative research is characterized by the collection and analysis of numerical data to identify statistical patterns and relationships. According to Creswell (2014), quantitative methodology is described as follows: "quantitative research can involve the use of instruments such as structured questionnaires, tests and measurements, and is oriented towards obtaining results that can be replicated and verified in different contexts" (Creswell, 2014).

Exploratory research is carried out when it seeks to explore a little-known or little-studied topic, aiming to better understand the problem and formulate hypotheses for future research (Cordeiro *et al*., 2024). Descriptive research, on the other hand, seeks to describe in detail a phenomenon that is already known and established (Pereira; By Miranda Silva, 2023).

The data survey was carried out in August 2024 based on notifications recorded by the Eye Bank of a city in the interior of the State of Rio Janeiro. The analysis covers the eye bank's internal spreadsheet of notifications of deaths and causes of exclusion in the year 2023, considering all notifications of death and causes of exclusion registered during this period.

The inclusion criteria for this study were the notification of deaths and the causes of exclusion for corneal transplantation.

The research involved three main stages: data collection was carried out through the

internal spreadsheet of the eye bank of notifications of deaths and causes of exclusion; and the notifications that became capture, where the information was extracted and organized in an Excel spreadsheet; quantitative analysis, which was performed to identify patterns and trends in the data, using bar graphs, pie charts, and tables to visually represent the information; and, finally, descriptive statistical analysis, which will provide a detailed view of the data by identifying frequencies and significant relationships between variables.

The organization of the data was carried out using an electronic spreadsheet software (Excel®) that facilitated the structuring of information in spreadsheets and the creation of graphs. These graphs and tables were essential for the detailed analysis, allowing the categorization of data such as the date of notification, the cause of death, and the reasons for the exclusion of potential donors. The analysis included visualizing the distribution of the causes of exclusion and other pertinent variables, providing a clear and detailed understanding of the data collected.

The final stage of the study involved the detailed interpretation of the data and the construction of thematic categories based on the identified causes of exclusion. The analysis was structured into three main categories: clinical factors, other reasons for exclusion, and monthly variations in causes of exclusion. The data were analyzed in accordance with the guidelines for quantitative research, allowing a thorough understanding of the notifications and causes of exclusion of potential cornea donors.

The use of the data was authorized by the Eye Bank, respecting the personal data protection guidelines.

The Brazilian Resolution does not consider this project research involving human beings and, therefore, the following cases are not evaluated by the CEP/CONEP System: Management and Process Improvement Studies, studies in which the focus is on improving an existing process in the sector or understanding environmental management practices. It is worth mentioning that in these studies, the object of evaluation is not the human being, but administrative information of the place to be analyzed.

RESULTS

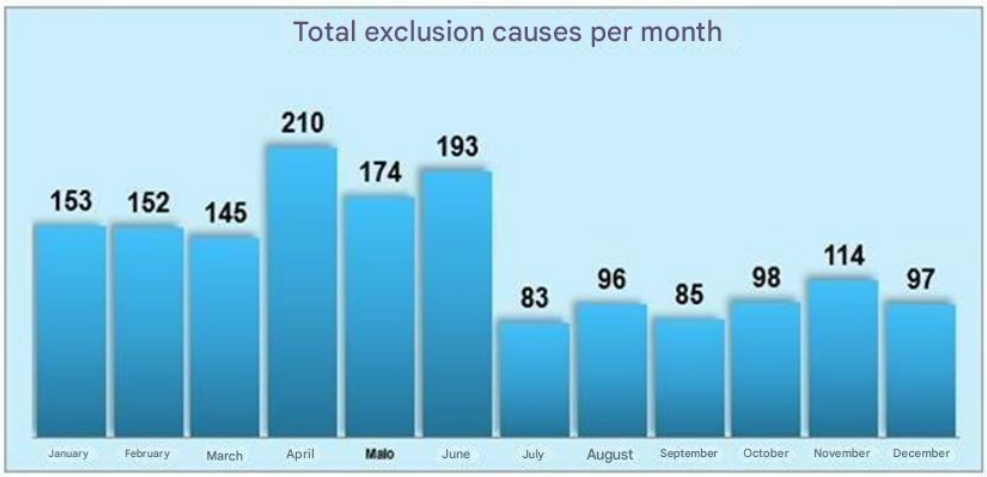
The present data analysis aimed to examine the main causes of exclusion of potential eye tissue donors throughout the year 2023 from an Eye Bank in the South of the State of Rio de Janeiro. From the outset, it was important to highlight that the available data were not complete in their entirety. Some causes of exclusion appeared only in certain semesters, such as sepsis, COVID-19, technical failure in collection, undetermined cause, maximum time for withdrawal exceeded, and issues related to the technician in processing,

which were concentrated in the first semester. Others, such as hepatitis and clinical and physical contraindications, occurred predominantly in the second half of the year, while causes such as HIV, restricted age group and logistics were present throughout the year.

The monthly analysis of notifications revealed occasional fluctuations throughout the year, with a total of 1600 exclusions recorded and an overall average of 148 monthly exclusions. In the first half of the year, the average was 171 notifications, with the months of April (210) and June (193) presenting the highest numbers of exclusions. In the second half of the year, the average fell to 95, with July recording a sharp drop (83).

The causes of exclusion for corneal investigation were diverse, with exclusion by age group standing out, which totaled 455 cases, evidencing compliance with current legislation.

Figure 1 - Exclusions



Source: Eye Bank of a city in the south of the State of Rio de Janeiro-2023

Another relevant factor was 422 cases of exclusion due to clinical contraindications, emphasizing the importance of prevention, maintenance, and evaluation of the donor's health before donation.

Sepsis, which registered 369 cases and, in the overall total, appeared as the third leading cause of exclusion, gained greater relevance in relation to a new time and statistical cut, as will be presented later.

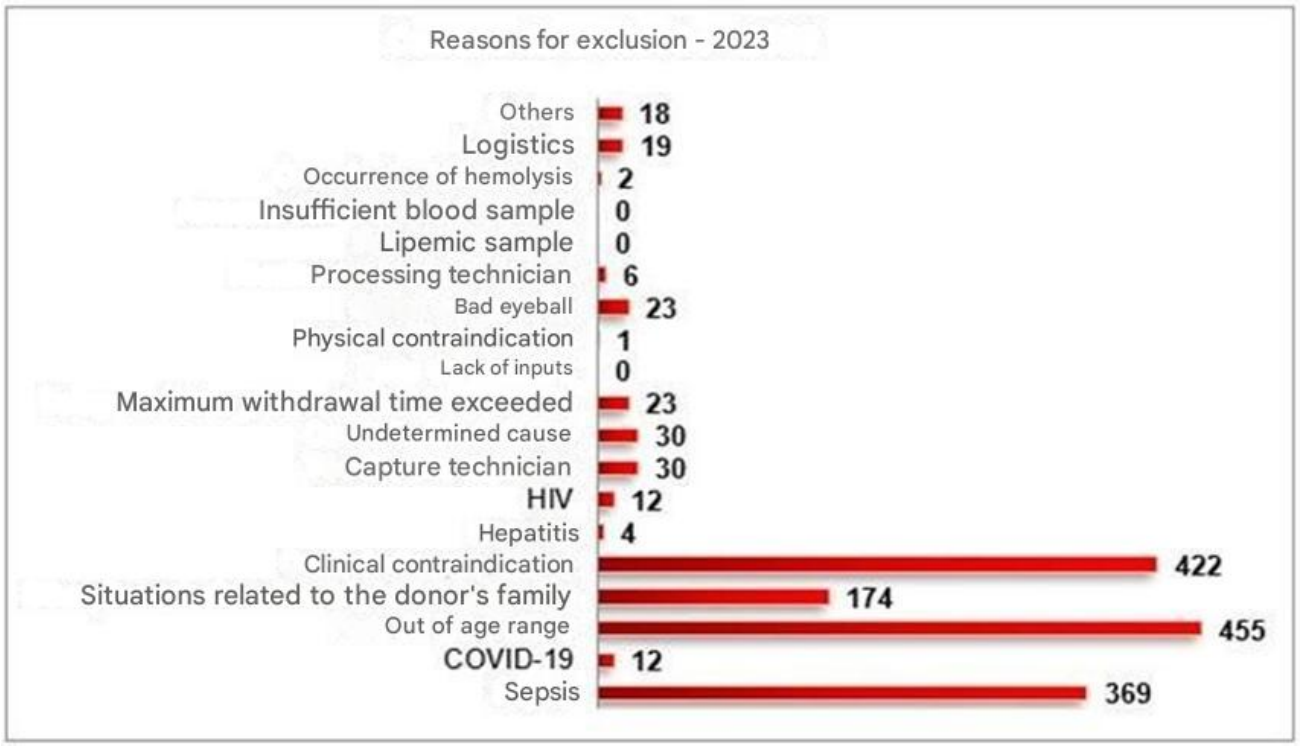
Situations related to the donor's family totaled 174 notifications, indicating that family factors influenced the decision about organ donation, or that they highlighted the need to raise awareness of this issue.

Other factors were also highlighted, such as COVID-19, which registered only 12 cases, reflecting a post-pandemic impact on donations. Exclusion due to poor eyeball totaled 23 cases, proving the importance of the preliminary evaluation of the quality of the

ocular tissue for the success of transplants.

Family resistance and lack of knowledge about the donation process also emerged as issues that needed to be addressed to improve the donation/fundraising offer.

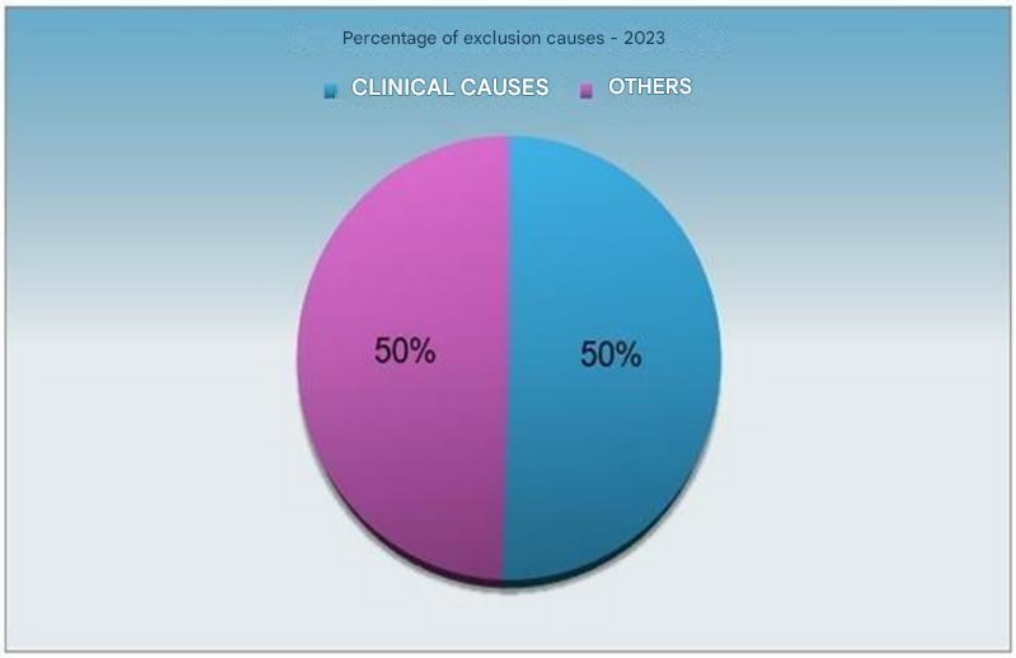
Figure 2 - Exclusions



Source: Eye Bank of a city in the south of the State of Rio de Janeiro-2023

The data indicated that exclusion due to clinical contraindications represented a significant challenge, requiring strategies to increase the importance of the donor's health conditions. When analyzing the clinical causes of exclusion — such as sepsis, clinical contraindications, hepatitis, HIV, and physical contraindications — it was observed that they represented a percentage equivalent to the sum of other causes of exclusion.

Figure 1 – Percentage of causes

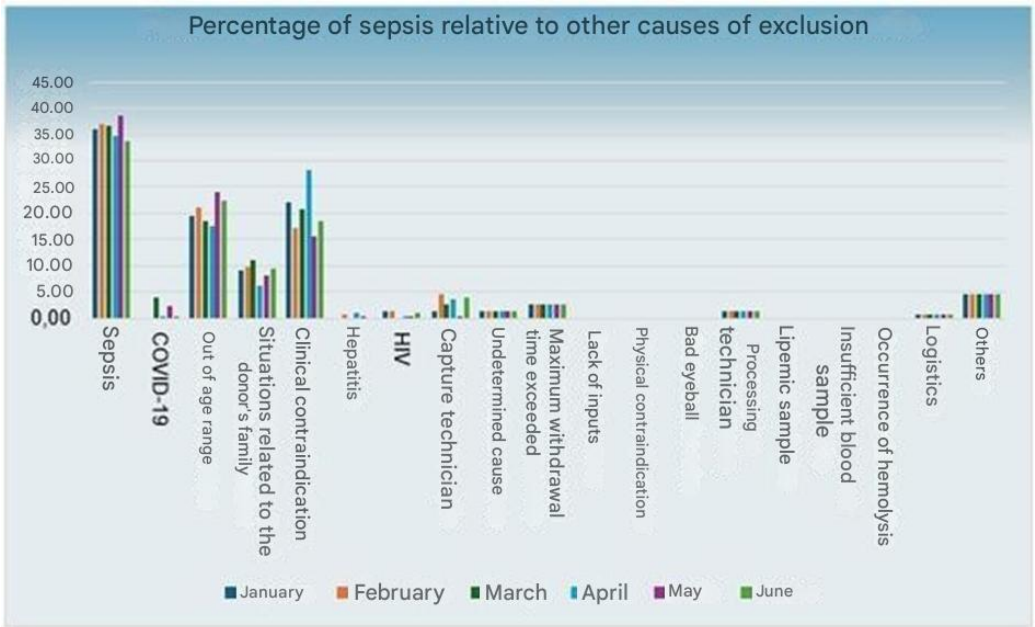


Source: Eye Bank of a city in the south of the State of Rio de Janeiro-2023

Three causes were identified with zero data: insufficient blood sample, lipid sample and occurrence of hemolysis, indicating that the collection of laboratory samples was efficient and did not interfere in the donation process.

An interesting fact dealt with sepsis, which was the third largest cause of exclusion in total, however, when comparing the percentage of incidence in the first semester, we will see that it became the largest exclusion factor among the causes.

Figure 4 – Analysis of Sepsis as a cause of exclusion



Source: Eye Bank of a city in the south of the State of Rio de Janeiro-2023

DISCUSSION

Exclusion by age group, the main cause of exclusion identified in the study, highlights compliance with current legislation according to Consolidation Ordinance No. 4, of September 28, 2017, Chapter VI, Section VII, art. 116, which established the age for eye tissue donation greater than or equal to 2 years and less than or equal to 80 years *(*Lima *et.al*.,2017). Such variation can be observed as a reflection of the population's due expectations rates between emerging and developed countries (Bezerra *et al*., 2024). Maintaining the age within the established parameters is important to guarantee the quality and viability of tissues for transplantation and creates reflections for the concern with the safety and efficacy of the procedures.

Clinical contraindications, such as sepsis, hepatitis, and HIV, were responsible for a significant part of the exclusions in ocular tissue donation. Ordinance No. 2,600, of October 21, 2009, CHAPTER VI, Art.. 47, 1st Paragraph ("The absolute criteria for exclusion of donors of organs, tissues, cells or parts of the human body are: HIV seropositivity; seropositivity for HTLV I and II; active tuberculosis; neoplasms, except for primary tumors of the Central Nerve System and carcinoma *in situ* of the uterus and skin; refractory sepsis; severe or potentially serious fungal infections in the presence of immunosuppression, except for hepatitis B and C) has established guidelines for contraindications, covering communicable infections and severe systemic diseases. According to the study by Jacques et al. (2019), which analyzed the main clinical contraindications for donation, these infections and other health conditions compromised the safety of transplants. There is the importance of strict criteria to ensure the viability (De Carvalho et al., 2024) and safety of donated tissues and emphasized the need for awareness of donation rules to increase the availability of organs and tissues.

The exclusion of donors due to infectious diseases, such as COVID-19 and hepatitis, conditions that pose a direct risk to the health of recipients, contribute to the safety of cornea donation and transplantation. Strict exclusion criteria for donors with infectious diseases, such as hepatitis and HIV, are essential to ensure the safety of corneal recipients, significantly reducing the risk of pathogen transmission (Pompeu, 2018).

From the records, it was observed that COVID-19 had less impact on donations, while hepatitis was more significant in the second half of the year. After the COVID-19 pandemic, the exclusion criteria for tissue donation were revised to include considerations about the transmission of the virus and the health of potential donors (Henrique; Souza; Carvalho, 2022). This highlights the importance of continued surveillance of infections as

an exclusion criterion.

Sepsis appeared as one of the main causes of exclusion. The monthly percentage of sepsis was higher than that of all other causes in the first half of 2023. An important detail was an adjustment of Ordinance No. 2,600 of October 21, 2009, updated in Consolidated Ordinance No. 4 of September 28, 2017, in which it began to treat as exclusion only sepsis in activity, and it is up to the Technical Responsible for the Tissue to verify the observation of the donation, through the donor's clinical data. According to Souza et al. (2021) states that the impacts of sepsis on organ donation, the pathophysiology of sepsis, the effects on organs, and the ethics of donation in cases of sepsis Although some organs may be considered viable in selected cases, sepsis should generally be considered a contraindication.

The cases related to family decisions reveal that there is a need for greater awareness, information campaigns and awareness about the process of eye tissue donation. It is necessary to develop more studies to understand family refusals and create strategies to enable a greater number of donations. Educational actions are essential for the explanation of the granting of organs. It is important to publicize this theme and to generate discussions about the subject in the family environment, considering that one of the obstacles to the realization of organ transplants is the family's lack of knowledge about the desire to be donors. According to Michel Cohen (2020) the challenges faced in family refusal to donate organs, analyzing the reasons behind these denials and proposing solutions to increase awareness and acceptance of donation within the family context, the importance of information campaigns and dialogue on organ and tissue donation is emphasized.

The maximum time for collection is another critical factor where the need for a more rigorous monitoring of the time elapsed between the death of the donor and the collection is suggested. Corneas should be harvested within 6 hours of death if the body is not refrigerated or within 24 hours if the body is properly refrigerated. Although Law No. 9,434/1997, with the amendment of Law No. 10,211/2001, establishes the beginning of the suspension of the term from the documented family authorization, technical standards such as RDC No. 67/2022 reinforce the need for compliance with these regulations to preserve the quality of the fabric. Thus, if the family's authorization occurs after 6 hours without body refrigeration, the donation becomes unfeasible due to the compromise of corneal quality.

Logistics involves challenges that need more descriptive data to understand the phenomenon. Understanding these aspects could increase the efficiency of corneal

harvesting. Several obstacles can be observed for the donation to be carried out, such as the logistics to enable the transport of the organ at the right time and in the appropriate place for conservation. According to Almeida *et al.* (2020) the logistical challenges faced in the organ donation process, including coordination between health teams, adequate organ transportation, and critical time management. There is a need for improvements in logistics practices to increase the efficiency and effectiveness of donation and transplantation, proposing solutions that aimed to optimize the entire process.

Causes of exclusion as a nursing technician in processing and recruitment may indicate the need for training and recycling, attributions for a specific continuing education. Continuing education enables nursing technicians to be constantly updated, contributing to the improvement of practices and to the improvement of the quality of care provided.

We cannot even rule out the possibility of a lack of human resources, as discussed by Pereira and Almeida (2022), who highlights the impact of the shortage of trained teams in tissue collection. Some more specific analyses were able to better discover this type of exclusion and create mechanisms to optimize them, as suggested in the annual reports of the Brazilian Association of Organ Transplants, which addressed the logistical challenges and the need for adequate sizing of organ and tissue procurement teams in Brazil.

The incompleteness of information in any of these categories poses a challenge for detailed analysis and strategic decision-making. Harel and Zhou (2007) argued that incorrect fillings could mask real causes of exclusion and compromise both the safety and efficiency of the donation and transplantation process. They also argued that the lack of reliable data could lead to inadequate decisions about the viability of organs and donors, compromising the safety of transplants and confidence in the donation system. The age limit, presence of infectious disease, logistical and structural problems, absence of professionals to interview the family after death, and family refusal were recognized as limiting factors in the donation process in the study and also identified according to Bezerra *et al*. (2024), it is necessary to adopt strategic measures to minimize limiting factors and increase corneal uptake.

FINAL CONSIDERATIONS

The results obtained in this study reveal a critical panorama of corneal harvesting in an Eye Bank in the South of the State of Rio de Janeiro, in the year 2023. In the analysis of declared death notifications in which the exclusions for corneal transplantation occurred mainly due to age group and clinical contraindications, sepsis was also evidenced as a cause of exclusion. These data indicate the urgent need for awareness campaigns on eye

tissue donation, since factors such as family resistance proved to be critical in this decision.

To improve the findings, it is suggested the implementation of continuous educational programs that address the importance of corneal donation and issues involving family refusal. The creation of informative materials, promotion of lectures and workshops in hospitals and communities, can increase awareness and, consequently, the ease of donation by families. It is essential to train health professionals, ensuring that they are able to conduct sensitive conversations about the action of organs with family members.

This research has weaknesses that should be acknowledged: the analysis was based on data from a single eye bank, which may limit the generalization of the results to other regions of Brazil. In addition, the incompleteness of some collected data and the monthly variations in the causes of exclusion indicate the need for more longitudinal studies that consider different periods and contexts. Future studies may investigate the relationship between donation awareness and the exclusion rate, as well as explore family dynamics in donation decisions.

Therefore, in the processes involving cornea donation, the nurse's performance has a direct impact on the efficiency and success of this action, whether in approaching the donor's family members, clarifying doubts and raising awareness about the importance of donation, or in coordination, interconnecting multidisciplinary teams, optimizing logistics, verifying current legislation, with the objective of increasing cornea donations and reducing exclusion factors.

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