

# Causes of death and discard of donated corneal tissues: Federal District eye bank analysis 2014 -2017

## *Causa mortis dos doadores e motivo de descarte das córneas: banco de olhos do Distrito Federal 2014-2017*

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### ABSTRACT

**Objective:** The aim of this study is to identify the causes for discarding corneas at the Eye Bank of the Federal District in Brasília, Brazil, and describe the social and demographic variables and Causa Mortis of cornea donors from 2014 to 2017. **Methods:** We conducted an exploratory and social-epidemiologic descriptive study regarding cornea donation. The data base information was obtained from the corneal donor's medical records analysis. All of the potential donors' records (cause of death, cause of cornea discard, month of donation, age, gender, and time of death, corneal enucleation and preservation), from 2014 to 2017 were included in the study. **Results:** We looked at 1,574 corneal donor notifications. Demographic characteristics displayed significant differences in gender distribution (male, 74.8% and female, 25.2%), and the average donor age was  $40 \pm 15.9$  years. 25% of the causes of death were from cardiovascular disease followed by 19.6% from sharp or blunt instrument injury, 14.2% resulted from multiple traumas. We described 3,074 donated corneas from the DF Eye Bank, where 2.6% has not been uptaken. Of those 3,074 corneal tissues, nearly 60% ( $n=1,836$ ) have been transplanted and 40% ( $n=1,238$ ) were discarded. Regarding the causes of discard, 68% ( $n=841$ ) were due to positive or indeterminate serological blood tests and 39% ( $n=486$ ) because of matureness (expired medium guaranteed period of corneal preservation). **Conclusions:** Specific issues such as violent causes of death, gender disproportion and total time of corneal processing can be better managed to reduce procurement times, and availability, of corneal tissue for transplantation.

**Keywords:** Cornea; Epidemiology; Eye bank; Corneal transplantation; Brazil.

### RESUMO

**Objetivo:** Identificar as causas do descarte de córneas no Banco de Olhos do Distrito Federal, em Brasília, Brasil, descrever as variáveis sociodemográficas e causa de morte dos doadores de córnea de 2014 a 2017. **Métodos:** Foi realizado um estudo descritivo exploratório e socioepidemiológico sobre as doações de córnea. As informações da base de dados foram obtidas a partir da análise dos prontuários dos doadores. Todos os registros dos potenciais doadores (causa da morte, causa do descarte, mês de doação, idade, sexo e tempo de morte, enucleação e preservação da córnea), de 2014 a 2017, foram incluídos no estudo. **Resultados:** Analisamos 1.574 notificações de doadores. Características demográficas apresentaram diferenças significativas na distribuição por sexo (masculino, 74,8% e feminino, 25,2%). A idade média dos doadores foi de  $40 \pm 15,9$  anos. 25% das causas de morte foram de doenças cardiovasculares, seguidas de 19,6% de perfurações por arma de fogo e 14,2% de múltiplos traumas. Descrevemos as 3.074 córneas doadas ao Banco de Olhos do DF e onde apenas 2,6% não foram captadas. Dos 3.074 tecidos da córnea, quase 60% ( $n = 1.836$ ) foram transplantados e 40% ( $n = 1.238$ ) foram descartados. Quanto às causas de descarte, 68% ( $n = 841$ ) foram devidas a exames sorológicos positivos ou indeterminados e 39% ( $n = 486$ ) por tempo de vencimento (período máximo de preservação da córnea). **Conclusões:** Questões específicas como causas violentas de morte, desproporção de gênero e tempo total de processamento da córnea podem ser melhor gerenciadas para reduzir o tempo de captação e a disponibilidade de tecido para transplante.

**Descritores:** Córnea; Epidemiologia; Banco de olhos; Transplante de córnea; Brasil

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## INTRODUCTION

It is estimated that 36 million people are considered legally blind and another 216.6 million people are classified as vision impaired worldwide.<sup>(1, 2)</sup> The main causes for these impairments are uncorrected refractive errors, representing 43%, and cataracts with 33% of the cases. In cases of blindness, cataract corresponds to 51%, glaucoma 8%, and 34% from other disorders.<sup>(3, 4)</sup> In this scenario, nearly 5.1% of vision impairment were caused by corneal opacities.<sup>(5)</sup> Trachoma, and vitamin A deficiency, sclerocornea, limbal cornea dermoids and keratitis are diseases which causes corneal opacities.<sup>(5, 6)</sup>

Cornea transplant is the most common and successful form tissue transplantation and is considered the primary treatment for restoring vision to patients with corneal blindness. Beyond those, keratoconus and Fuchs' dystrophy are the most important pathologies to use corneal transplant as treatment strategy.<sup>(2, 7)</sup> Corneal transplants have been performed all over the world and in 2012 alone almost 184,576 were done in 116 countries.<sup>(3)</sup> Of those, 8% (nearly 15,000) were performed in Brazil, which, is a leader in tissue and solid organ transplantation worldwide by the public health system (SUS).<sup>(3, 4, 8)</sup>

From 2010 to 2017, 113,219 corneal transplants were performed in Brazil, which is significantly higher than other solid organs transplantation such as kidney (43,224) and liver (12,038).<sup>(9, 10)</sup> Beyond the increasing numbers of corneal transplantations, the procurement process has also increased when compared to transplantation per capita rate.<sup>(3, 11)</sup> Until December of 2017, 9,266 patients were on the general waiting list for corneal transplants in Brazil and 2.14% (199/9,266) of those are from the Federal District (DF).<sup>(10)</sup> From 2009 to 2016, the number of potential donors grew 36.10%, but the proportion of effective and potential donations increased only 3.8%, so the challenge of improving the donor selection process is still important.<sup>(12, 13)</sup>

The collection, processing and distribution of corneal buttons is the responsibility of the Eye Banks (EB), part of SUS, which organize their workflow in accordance with the Pan American Association of Eye Banks (APABO) and the Eye Bank Association of America (EBBA). The standardization of procedures by the EB are necessary once they have had a direct influence on the final quality of the cornea tissue and, consequently, the post-operative success.<sup>(2, 11, 14)</sup>

The National Agency for Health Surveillance (ANVISA) in Brazil regulates the Eye Banks work through the "Resolução da Diretoria Colegiada" (RDC) n° 55/2015,<sup>(15)</sup> available on the institution website. This legal rule standardizes the potential donor selection process using the family interview, medical records analysis, the deceased body evaluation and the tissue quality itself.<sup>(14, 15)</sup> The total cost of family interview, harvesting and processing the corneas by the eye banks is paid by the public health system. The cornea tissue cannot be sold or be part of any kind of financial transaction. Transplantations costs made outside of SUS health services, must have private resources except for the tissue which is donated.<sup>(15)</sup> Because of the infectious and transmissible diseases risks, the RDC n° 55/2015 also establishes the tissue contraindication parameters, such as the donor serological tests for tissue approval for transplantation.<sup>(16)</sup>

The aim of this study was to identify the causes for discarding corneas from the Eye Bank of the Federal District

and to describe the social and demographic variables and cause of death of corneal donors from 2014 to 2017.

## METHODS

We conducted an exploratory and descriptive study regarding cornea donation to the DF Eye Bank located in an important tertiary public hospital. The DF Eye Bank was founded in 2003 as a non-profit entity, which conducts active searches for donations within the Instituto Hospital de Base do Distrito Federal (Latitude: 15° 46' 48" S, Longitude: 47° 55' 45" W), which is in the Central-Western region of the country and has a population of approximately 3 million people. This information is available on the Brazilian Institute of Geography and Statistics (IBGE) website.<sup>(17)</sup>

The project was approved by the Ethics Committee for Human Experimentation of DF Health Secretary and the Health Sciences Faculty (University of Brasília) under the 158 protocol number CAAE45898115.8.0000.0030.

The data collection was performed through analysis of corneal donor's medical records, and organized in a database using Excel software (Microsoft Corporation, USA).

All the potential donors' characteristics (cause of death, cause of cornea discard, month of donation, age, gender, time interval of death, corneal enucleation and preservation) from 2014 to 2017 were included in the study. We processed and analyzed the data using the Statistical Package for Social Science software (SPSS) (IBM, USA). The collected information was described as measures of frequency and absolute numbers and percentages. For the results analyses the Pearson chi-square was used ( $P < 0.05$ ) to comparison between the analyzed years and non parametric Wilcoxon test to compare the time intervals T1 (between time of death and the eye globe enucleation) and T2 (between eye globe enucleation and cell medium preservation) over the time. All the statistics tests used  $p$ -value  $< 0.005$ .

## RESULTS

From 2014 to 2017, we observed 1,574 corneal donor notifications at DF Eye Bank Institution and 1.77% (28/1,574) of them were excluded from the medical records analysis because they did not have all the variable information. The year 2015 had the highest number (29.3%,  $n=454$ ) of donations and 2017 had the lowest (21.6%,  $n=335$ ) though they also had the greatest number of excluded registrations (16/28) (Table 1). Demographic characteristics showed disproportionate in gender distribution between male (74.8%,  $n=1,157$ ) and female (25.2%,  $n=389$ ), as shown in Table 1.

The average donor age during the studied period was  $40 \pm 15.9$  years (Table 1). The

age range of the majority of cornea donors was 51-60 (21.9%) but the 41-50 (21.5%) age range had almost the same number of donors, and all of them presented the same variation throughout the observed period, including those two most representative ranges cited below (Table 2).

By each year month were observed cornea donation average about  $128 \pm 29.3$  per year.

The aggregate data demonstrated that June presented the biggest number of donations over the past 4 years as shown in Figure 1.

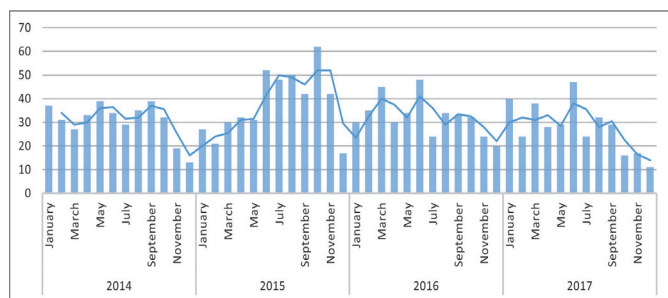
**Table 1**  
**Demographic characteristics from cornea donors**

Year	Age		Female		Male		Total		p-value†
	Mean	SD	N	%	N	%	N	%	
2014	40	± 16.2	91	24.7	277	75.3	368	100	Reference
2015	41	± 15.6	118	26.0	336	74.0	454	100	0.679
2016	39	± 16.1	86	22.1	303	77.9	389	100	0.405
2017	41	± 15.1	95	28.4	240	71.6	335	100	0.305
<b>Total</b>	<b>40</b>	<b>± 15.9</b>	<b>389</b>	<b>25.2</b>	<b>1157</b>	<b>74.8</b>	<b>1546</b>	<b>100</b>	

† Chi-Square (df=1). p-value: Chi-square comparison between years SD: Standard Deviation

**Table 2**  
**Age Distribution of Cornea Donors from the DF/Brazil Eye Bank of Brazil**

Age range	2014		2015		2016		2017		Total	
	N	%	N	%	N	%	N	%	N	%
≤10	5	1.4	4	0.9	7	1.8	9	2.7	25	1.6
11 - 20	51	1.9	63	13.9	70	18.0	37	11.0	221	14.3
21 - 30	74	20.1	68	15.0	54	13.9	46	13.7	242	15.7
31 - 40	59	16.0	69	15.2	59	15.2	47	14.0	234	15.1
41- 50	64	17.4	107	23.6	74	19.0	87	26.0	332	21.5
51- 60	73	19.8	95	20.9	96	24.7	74	22.1	338	21.9
61-70	40	10.9	48	10.6	29	7.5	35	10.4	152	9.8
≥ 71	2	0.5	0	0.0	0	0.0	0	0.0	2	0.1
<b>Total</b>	<b>368</b>	<b>100</b>	<b>454</b>	<b>100</b>	<b>389</b>	<b>100</b>	<b>335</b>	<b>100</b>	<b>1546</b>	<b>100</b>



**Figure 1:** Corneal donations monthly distributed.

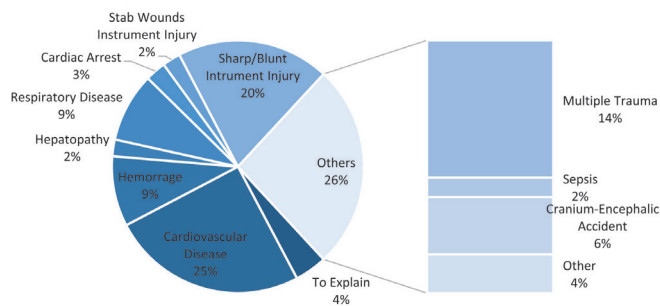
**Table 3**  
**Comparison between the time of death, enucleation and preservation interval**

Interval period	2014		2015		2016		2017	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
T1	7.7	5.5	7.3	4.7	7.3	5.3	7.4	4.9
T2	6.7	4.6	6.7	3.9	6.2	3.9	6.7	4.3
<b>Total (T1 to T2)</b>	<b>8.2</b>	<b>5.2</b>	<b>8.4</b>	<b>5.0</b>	<b>8.0</b>	<b>4.6</b>	<b>9.2</b>	<b>5.6</b>

T1= Time between death and enucleation (in hours)  
T2= Time between enucleation and preservation in medium (in hours)  
SD = Standard Deviation

In the T2 comparison, we observed an increase between 2016 and 2017. The median values and comparison between the total time of corneal processing (from the moment of death until medium preservation) is not significantly related to the causes of death according to the result of the independent-sample median test, p value = 0,114. The statistical comparison between T1 and T2 for the same year are different according to the related-sample Wilcoxon signed rank test result, p value <0,001. Therefore, they are different from each other, and evidenced by the increase of total time of 9.2 hours in 2017 when compared to 2014, demonstrating that in 2017, the T2 intervals had more hours than the T1.

The causes for discarding corneal buttons' were distinguished in two different groups, one containing all the systemic causes, and the other ophthalmic or tissue intrinsic causes. 3,092 corneas were donated to the DF Eye Bank from 2014 to 2017 and 3% (n= 18/3,092) have not been uptaken. So, in total 3,074 corneas were uptaken and processed by ANVISA's orientation(15), nearly 60%



**Figure 2:** Cornea donors' causes of death.

Brazilian law establishes a legal requirement to collect eye tissues only within 6 hours after death. The time intervals between death and eye globe enucleation (T1) and between eye globe enucleation and corneal button preservation in medium storage solution (T2) demonstrates that T1 averages in 2014 were 7.7 hours (h) and have decreased over the years to 7.3 h in 2015 and 2016 and 7.4 h in 2017 as shown in table 3.

(n=1,836) were transplanted and 40% (n=1,238) were discarded. As shown in table 4, the major causes of discard from systemic causes were positive or indeterminate serological tests (68.3%, n=424) and indeterminate donor's causa mortis (14.4%, n= 90). For the corneal self-tissue, the most prevalent causes of discard were matureness, which is the exceeded time of tissue preservation storage, with 39.3% (n=245) and stromal infiltration with 37.2% (n=232). Considering that each donor has two corneal tissues, the number of samples not taken up (n=18) demonstrates the case that only one corneal tissue was preserved and the other

**Table 4**  
**Causes corneal tissue discard**

<b>Sistemic causes</b>	<b>N</b>	<b>%</b>
Infectious causa mortis (sepsis)	58	9,3
Cancer	2	0,3
Indetermined causa mortis	86	13,8
Contraindication	15	2,4
Positive or Indeterminate Serology	424	68,3
<b>Total</b>	<b>585</b>	<b>47,0</b>
<b>Ophthalmic causes</b>		
Non-biological artifact	82	13,1
Stromal infiltrate	232	37,2
Corneal leukoma	1	0,2
Non-viable tissue	40	6,4
<b>Total</b>	<b>355</b>	<b>28,5</b>
<b>External causes</b>		
Technical failure	8	1,3
Inadequate serological samples	27	4,3
Not uptake	18	2,9
Matureness	245	39,3
<b>Total</b>	<b>298</b>	<b>23,9</b>

was not.

## DISCUSSION

The gender distribution results are similar when compared with data previously described by our study group, such as 73.3% for male and 26.5% for female from the 2004 to 2013 analysis.<sup>(4)</sup> Other studies worldwide have described different results; some of them with greater discrepancies<sup>(18, 19)</sup> and others with more equal proportion between genders.<sup>(20-22)</sup> Despite this, the male gender is almost always the largest proportion among all studies, principally due to the fact that they are the main victims of external causes of death.<sup>(23)</sup> Violent and non-violent causes of death may influence the discrepancy between genders among the population in the Federal District. External

causes of death are expected, and have been discussed previously by this work group.<sup>(4,18,23)</sup> Hopkinson et al.<sup>(24)</sup> proposed that gender can influence the donor and recipient incompatibility related to corneal rejection and failure, thereby, the gender distribution information is used to improve technical procedures, health policies and clinical conduct.

The mean donor age of our study was  $40 \pm 15.9$  years (Table 1) consistent with other recent studies,<sup>(4,18,20)</sup> but still lower than other national and internationally published studies.<sup>(21, 25-28)</sup>

From 2014 to 2017, the month of December had the lowest

absolute number of donations, at least half (3.9% n= 61) when compared to the rest of the year's average as shown in Figure 1. Systematic monthly information regarding donations of corneas collected throughout the year and compared with other years improves the physical, technical and financial management of the eye bank.<sup>(29)</sup> The scientific literature regarding epidemiological analysis of cause of death, for corneal tissue donors, demonstrates heterogeneity of those causes nomenclature and classifications. Therefore, in order to analyze these types of results in a general way, the etiological cause of death must be considered even if the Eye Bank Association of America (EBAA) has established their own unique classifications.<sup>(30)</sup> In light of that, the most frequent causes of death were cardiovascular diseases (25.1%, n=388) (Figure 2), which was previously described in the state of São Paulo<sup>(21,31)</sup> and Cascavel city (Paraná State)<sup>(28)</sup> in Brazil and agrees with U.S Eye Banks results from 2011 to 2016.<sup>(30)</sup> Thus, other studies have also demonstrated the frequency and importance of the heart or cardiac disease as significant non-external cause of death, some with minor and others with higher representative results.<sup>(4, 25, 32)</sup> The second most observed external cause of death was sharp/blunt instrument injury (19.6%) which was also described in DF, Brazil by our group, as well as worldwide.<sup>(18, 19, 27, 33)</sup> The historical and increasing prevalence of this type of death may reflect the violent social environment in Brazil.<sup>(18, 23, 28)</sup> ANVISA's RDC n° 55/2015 establishes the maximum range for time interval between death, eye globe enucleation, corneal preservation and storage conditions. The results observed in Table 3 showed a slight decrease in T1 interval from 2014 to 2017 and maintenance of T2 results. Overall average from time between and preservation was homogeneous throughout the analyzed period. The average time for the same period from the state of Goiás ( $6.5 \pm 4.3$  hours) is lower when compared to our results.<sup>(18)</sup>

The main concern is that this average (7.7–7.4 hours) does not comply with ANVISA's standardized time.<sup>(15)</sup> This T2 average and the total (T1+T2) time increased in 2017 (9.2 hours), when compared to 2014, 2015 and 2016, and resulted from the necessary changes to the adequacy of the Bank's services per the new ANVISA RDC n°55<sup>(15)</sup> legal standards in 2015. Although Eye Bank studies in São Paulo have not observed any difference in the total time interval average, they have shown lower quality tissue samples.<sup>(34)</sup> The impact is the major chances of corneal epithelial defects, exposing the tissue to traumatismes and decreasing their quality to transplant.<sup>(34)</sup> Some studies demonstrated the proportion of discarded and transplanted cornea tissue as about 10-16.3% in São Paulo, 21.9% in the state of Rio Grande do Norte<sup>(35)</sup> and 24% in the state of Minas Gerais.<sup>(36)</sup> Table 4 shows that we observed almost 40% (n=1,238) discard rate in the Federal District, a higher result when compared to São Paulo and Rio Grande do Norte, and even the global average,<sup>(37)</sup> about 35%, but lower than the state of Ceará at 49.1%.<sup>(38)</sup> In general, the causes for discarding are distributed and separated into three different groups: systemic, ophthalmic and external causes.

Several studies have described positive diagnosis by blood screening for infectious diseases. Once all potential deceased organ donors are serologically screened<sup>(15, 16)</sup> for HIV-1 and -2 antibody, human T cell lymphotropic virus (HTLV)-1 and -2 antibody, HCV antibody, Anti-HBc and HBsAg, the results of infectious disease prevalence are described in Brazil<sup>(14, 19)</sup> and worldwide.<sup>(39)</sup> Therefore, corroboration with positive or undetermined serological results are the major cause of cause



of discarded corneal tissue (68.3%. n=424) from our study. Despite the lower rate of positive cornea donor samples, compared to 20% worldwide<sup>(39)</sup> and 1- 32% in local states,<sup>(14,27,28)</sup> our results consider all the undetermined serological results that could explain the rate of increase when compared to others. The reduced availability of validated serological cadaveric tests has been discussed as a possibility for false-positive results related to discrepancies between in vivo and postmortem serological performance.<sup>(4,16)</sup>

Analyzing social, demographic and technical indicators, using statistical tools to correlate epidemiological data, mitigates the improvement of public health measures of transplant centers and consequently improves the population's access to the quality service. The total cost of family interview, harvesting and processing the corneas by the eye banks is paid by the public health system (SUS) the entire cost of the family interview, harvesting, and processing by the eye bank is paid by the public health system (SUS).

The Eye Banks have a new challenge to enhance safety and effectiveness of corneal transplantation. As discussed in this study, some specific issues such as violent causes of death, gender disproportion and total interval time of corneal processing management seek to reduce those procurement processes and increase availability of corneal tissue for transplantation. The donor's medical records analysis, personal clinical history, serological screening tests and tissue evaluation are influential factors for effective corneal transplantation. In this study, we noticed the significance of standardizing some Eye Bank procedures. We observed that the cause of death and discard classification is not standardized and as a result, it shows a heterogeneity of nomenclatures. For an effective data analysis, a reclassification based on etiological causes and guided by the Brazilian Ministry of Health's technical document "The death certificate: a necessary and important document"<sup>(40)</sup> is highly recommended.

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#### ERRATA

In the scientific article “**Causes of death and discard of donated corneal tissues: Federal District eye bank analysis 2014-2017**” by authors: **Diogo Souza Loiola, Sônia Nair Bão, Thayssa Neiva da Fonseca Vítter, Micheline Borges Lucas, Maria Regina Catai Chalita, Thatiane Lima Sampaio**, published in issue number 4 - volume 78 of the *Revista Brasileira de Oftalmologia*, July-August 2019, pages 227-32, DOI 10.5935/0034-7280.20190133 was published incorrectly in the order of the author names. **Where it reads:** Diogo Souza Loiola, Sônia Nair Bão, Thayssa Neiva da Fonseca Vítter, Micheline Borges Lucas, Maria Regina Catai Chalita, Thatiane Lima Sampaio, **reads:** Thayssa Neiva da Fonseca Vítter, Diogo Souza Loiola, Micheline Borges Lucas, Maria Regina Catai Chalita, Thatiane Lima Sampaio, Sônia Nair Bão.