# Project of Cornea Donation in Rio de Janeiro: Analysis of the Implementation of an Organization Innovation Practice

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ABSTRACT

Background. For many cornea disorders, transplantation can be the treatment of first choice. In Brazil, there is a disparity in the number of transplants between regions due to the lack of an oriented system for cornea procurement.The aim of this study was to analyze the implementation of a system exclusively oriented toward the improvement of cornea recovery in the Rio de Janeiro State Organ Procurement Organization (OPO) area. With this system, all cornea donation activities were coordinated by the OPO after telephone referrals following asystolic death. From the perspective of health care innovation, we will discuss the role of the main participants and their interactions following the implementation phase.

Methods. One hospital was chosen to host the project following the first 2 years of the implementation of the State Cornea Donation System. We retrospectively analyzed all deaths between January 1 and December 31, 2016, using the hospital death records and the OPO referrals record. The strategic plan, documents, and interviews were carried out for the analysis of the implementation of this innovation in our region.

Results. Of 1720 deaths in 2016, 1093 (63.5%) were referred to the OPO following asystolic death for assessment and screening, but 819 of these potential tissue donors (PTDs) were not eligible for donation due to medical contraindications. The remaining 274 (25.1%) fulfilled the PTD criteria. Less than half of the families (n = 128) of these PTDs could be contacted requesting donation, but 50% consented. Finally, corneas were procured from 58 patients. The interactions between in-house coordinators and top managers were mandatory for the success of program implementation.

Conclusion. For the first time in our country, cornea recovery took place following asystolic death with OPO coordination at a central level. The PTD rate could be estimated, and an analysis of the role of stakeholders could be made for the implementation phase of this innovation in our system.

CORNEA transplantation is reported as one of the oldest transplant procedures, with the first surgeries performed in the 1930s [1]. Despite corneal transplantation being the most frequent surgery among all types of transplants, cornea diseases are still the major cause of vision loss, producing psychological and economic consequences for the individual and society as a whole [2].

In many countries the number of corneas procured is insufficient to meet the demand for transplants for several reasons. These include poor identification and referral of potential tissue donors (PTDs), medical contraindication, and family refusal and logistical issues, with the last one representing the main cause of inefficiency [3–5].

In Brazil, the number of cornea transplants has been decreasing since 2012, as has the number of patients on the waiting list. In 2014, 13,000 (68.3 transplants pmp) were

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performed, while the estimated annual demand was more than 17,000 (89 transplants pmp). There is still a disparity in the number of transplants between regions in Brazil, varying from 136.6 pmp (Brasília, Federal District) to 14.7 pmp (state of Rondônia) [6].

An improvement in organ donation has taken place in Rio de Janeiro since 2010, with the deceased donor rate increasing from 5.1 pmp in 2010 to 17.0 pmp in 2014. This shift was due to a new organizational model for organ procurement through the launch of a remodeled State Organ Procurement Organization (OPO)—the Programa Estadual de Transplantes—but the strategy to increase the number of brain-dead donors (DBDs) was unable to meet the demand for corneas and other tissues [7,8]. Until 2014, all transplants were performed from tissues recovered from DBDs. In the same period, 301 cornea transplants were performed (18.8 pmp), while the estimated demand was more than 1400 surgeries [6].

The objective of this study was to analyze the implementation of a system exclusively oriented toward the improvement of cornea recovery and the results of the system following the first 2 years. From the perspective of health care innovation implementation, we will discuss the role of the main participants and their interactions from conception through implementation effectiveness.

## IMPLEMENTATION OF A STATE CORNEA DONATION SYSTEM

In 2014, a strategic plan was made to implement a cornea donation system in the state of Rio de Janeiro, with the first goal being to increase cornea recovery and transplantation through donation following asystolic death. The main stakeholders were identified: the OPO, tissue banks, and general hospital staff.

The objective was to set up an innovation in the local health care system that consisted of telephone referrals from local hospitals to the OPO of all deaths following cardiac arrest. Thus, the OPO should coordinate at the central level all tissue donation activities. Every PTD should be identified—that is, any deceased person with no medical contraindication for tissue donation and from whom blood samples could be obtained for serologic tests [9].

Since it has been demonstrated that the PTD rate varies from 18% to 40% among all hospital deaths, it was hypothesized that this strategy could maximize cornea donation across the state [9–11]. In fact, timely referral to an OPO following asystolic death already a standard practice in some procurement organizations worldwide, but it had never been done in Brazil with this level of commitment. It has been demonstrated that this practice provides an efficient cornea recovery system [5,12].

The OPO Cornea Team started operating on January 1, 2015. Ten professionals, including physicians, nurses, and social workers, were admitted to the team to work in 24-hour shifts as OPO transplant coordinators, doing assessment and screening by phone of all deaths reported by hospitals. When a PTD is identified, the OPO must coordinate the interface between the hospital staff, through its in-house coordinator (IHC), and the tissue bank that will perform the recovery. Two ophthalmologists were responsible for training, education, and supervision of nonmedical staff.

At the hospital level, one of the main trauma centers in the state, Hospital Estadual Adão Pereira Nunes (HEAPN), was chosen to host the pilot project due to its characteristics and high performance in organ donation in the past years. In this hospital, 4 IHCs were working fully dedicated to organ donation as a result of a health policy implemented a few years before [7].

In fact, there was a previously unsuccessful project for cornea retrieval in progress at the hospital, which had been implemented in January 2013. By that time, the tissue bank had set up a cornea recovery team to work inside the hospital in 24-hour shifts to detect PTDs and to recover corneas. No corneas were recovered from cardiac-arrested patients; they were recovered only from brain-dead patients. There was little engagement of hospital staff in cornea procurement and no relationship between the recovery team and the hospital's director board beyond a formal consent to the activities.

Considering the poor performance and the need for improvement, it was assumed that the engagement of the IHCs with a higher level of support from the top managers would be crucial. In April 2015, the tissue bank cornea recovery team was dismissed, and several meetings between the top managers from the OPO, the tissue bank (Banco de Olhos do Hospital São João Batista), and the hospital were held to implement the innovation. The initial aim was to sell the innovation to the hospital's top management team (TMT) and get their commitment in the assimilation process. It was assumed that this would help to effectively implement the innovation [13].

With TMT support, all IHCs were highly involved and trained for adequate assessment of PTDs, physical examination of tissue samples, and obtaining blood samples after cardiac arrest from a central vein or the heart, if necessary. At the same time, lectures and basic training were held for all hospital staff with the aim of engagement toward cornea donation. A protocol was established for referral of all deaths in real-time to the OPO.

## MATERIALS AND METHODS

We retrospectively analyzed all deaths between January 1 and December 31, 2016, using the hospital death records and the OPO referrals record. The hospital death records worksheet inputs were name, hospital ID number, age, time of death, department, and cause of death. The IHC also registered whether a family request was made and, if no donation was made, the reason for that. The OPO record had the same inputs, but it was limited to deaths referred from hospital staff.

A comparison of hospital death records with OPO referral records was made to identify missed referrals. For estimating the number of PTDs and the potential of the hospital for cornea

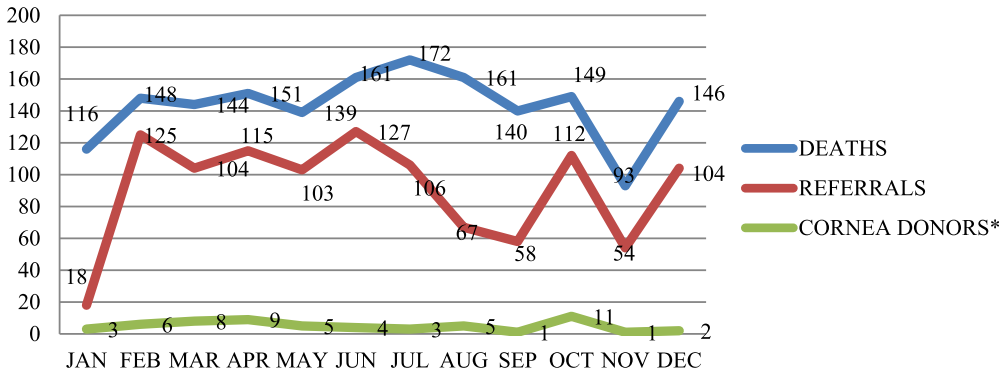


**Fig 1.** Number of deaths, referrals to the OPO, and cornea donors from January to December 2016 at the hospital (HEAPN). *Corneas procured from brain-death donors are not included in this figure, as this activity is not influenced by the protocol examined in this report.

donation, death causes were grouped into 6 categories: infectious, neoplasia, cardiovascular disease, trauma, undetermined, and others.

The strategic plan and other relevant documents were gathered. The main participants from the IHCs, OPO, and tissue bank were interviewed to clarify there interactions and roles in the project during the implementation phase.

## RESULTS

Figure 1 summarizes the number of cornea donors from January to December 2016 at HEAPN procured by this protocol. The main steps of innovation implementation described above are also summarized. Of 1720 deaths in this period, only 1093 (63.5%) were reported to the OPO for assessment and screening by phone, with subsequent physical examination and family approach by either the IHC or tissue bank staff.

Of the 1093 deaths referred to the OPO, 819 were not eligible for donation due to a medical contraindication (74.9%), having been assessed clinically by a transplant coordinator or staff from the tissue bank. The remaining 274 patients (25.1%) fulfilled the PTD criteria.

Of the 274 PTDs assessed, 102 families did not receive requests for tissue donation due to lack of infrastructure, and in 44 additional cases, the family could not be found. In total, 128 families received requests for donation, and 50% of them consented for cornea donation. From the 64 authorizations obtained, corneas were procured from 58 patients.

We retrospectively analyzed all deaths (n = 1720) from the hospital death reports to estimate the losses due to missed referrals. From this analysis, 1027 patients (59.7%) had a clear medical contraindication for cornea donation, including sepsis, some specific types of cancer or risk group, or infection with human immunodeficiency virus or hepatitis B or C virus. The 693 remaining patients classified as PTDs would be, in theory, eligible for cornea donation.

Figure 2 summarizes the main causes of death at HEAPN during 2016. The main cause was infection of any type (n = 595, 35%), following by cardiovascular disease (n = 334, 20%) and trauma (n = 253, 15%).

Figure 3 demonstrates the number of cornea donors during the first 2 years of the project. In 2014, no corneas were retrieved from cardiac-arrested patients despite the maintenance of the tissue bank cornea recovery team. In 2015, 44 corneas were retrieved from 22 donors following asystolic death, and the following year showed a growth of 163%, with 116 corneas retrieved from 58 donors following asystolic death.

## DISCUSSION

A shortage of tissue grafts, as corneas, skin, vessels, and bones, is a reality worldwide. The lack of donor tissue procured is the limiting factor for treating many diseases. Endothelial abnormalities and keratoconus represent the leading indications for cornea transplantation [14,15].

Apparently, the lack of a tissue donation oriented system seems to be the main reason for the inefficiency in many countries and regions, due to its peculiarities. In the state of Rio de Janeiro, the OPO launched in 2010 was initially focused on maximizing the number of DBDs, from whom both organs and tissues can be recovered. There was a substantial increase in the number of cornea transplants when 2009 is compared to 2014, with 88 (5.7 pmp) procedures performed in 2009 and 301 (18.8 pmp) in 2014 [6,8]. The number of surgeries was still below the necessity,

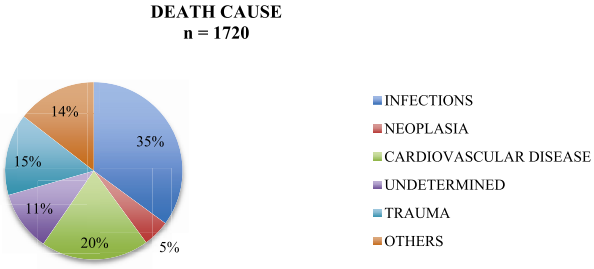


**Fig 2.** Main death causes at the hospital (HEAPN) in 2016.

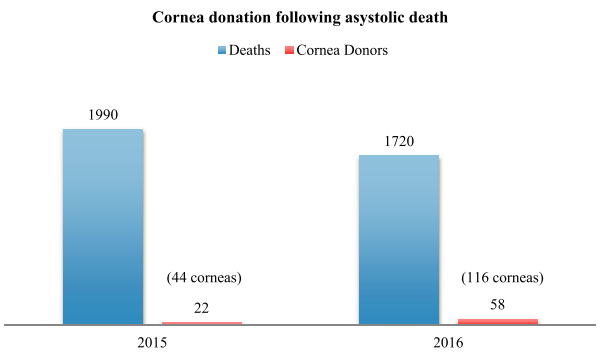


**Fig 3.** Cornea donations following asystolic death.

however, as it had already been demonstrated that the number of brain-dead patients was insufficient to meet the demand for corneas. Brain death is a rare event, representing only 0.5% to 1% of all deaths in a population [16,17].

Studies have demonstrated a considerable variability in the rate of PTDs (any deceased person with no medical contraindication for tissue donation and from whom blood samples can be obtained for serologic tests) in different regions, varying from 18% to 40% among all deaths, according to hospital profiles [9–11]. So, except for medical contraindications, logistical issues represent the main cause for inefficiency in this process. These include low or no referral of deaths to the IHCs or the OPO, early removal of the body from the morgue, inability to cool the body in proper temperature, unavailability of the recovering room due to autopsy; unavailability of the recovering team in time for the procurement, and inability to contact or meet the family of the deceased patient [4].

Implementing a cornea donation system oriented toward detection, screening, and adequate timely assessment of PTDs is a challenge, especially in our reality, where the main hospitals are public and most of their staff are unaware of this activity. This is the main reason that we wanted to perform this study, to describe the steps of the implementation and the results and correlate them with the literature of health care innovation implementation so that new theoretical constructs can be identified and applied to clinical practice in the future.

As mentioned before, HEAPN is one of the main trauma centers in the state of Rio de Janeiro. Since 2012, the hospital has been developing strategies to improve organ and cornea donation rates. In that facility, there is a highly skilled and fully dedicated IHC team composed of 1 physician and 3 nurses. Despite this, performance with regard to cornea donation following asystolic deaths was negligible. Cost had increased in 2013 when the tissue bank decided to hire professionals, but the results were still unsatisfactory.

In 2015, the OPO was involved together with hospital top managers, and, finally, the IHC work routines were rebuilt, especially with the designation of one of the nurses for cornea donation activities. Then, as shown earlier, the cornea donation rates improved and cost was reduced at the hospital level. At the OPO level, a highly specialized team was settled on in anticipation of a bigger demand in the future, when more hospitals and activities should be integrated to generate more corneas for transplantation.

It is important to highlight that missed referrals from HEAPN accounted for the loss of detection of more than 400 PTDs, since 36.5% of all deaths were not reported to the OPO. Lack of infrastructure is still a major cause of the lower conversion rate following PTD identification. Thus, with optimization of referral activity and performance improvement, it may be possible to reach up to 300 cornea donors every year.

As a result of the change in mentality throughout the whole system, the number of transplanted corneas in our region increased from 301 (18.8 pmp) in 2014 to 575 (34.7 pmp) in 2016. The State Cornea Donation System resulted in an improvement of more than 90% in cornea transplantation following the first 2 years of implementation.

### Analysis From a Health Care Innovation Implementation Perspective

Innovation is defined as “an idea, practice, or object that is perceived as new by an individual or another unit of adoption” [18]. Health care is rich in evidence-based innovations, yet despite a successful implementation in one facility, many cases of innovation may disseminate slowly [19].

For organ and tissue transplantation, a huge effort has been made worldwide toward the dissemination of best practices through benchmarking and innovation implementation [20]. In spite of this effort, there is still a huge difference among countries, with multiple factors influencing donation and transplantation activities, such as economics, politics, and sociocultural behavior, which are also affecting other innovations in health care [21,22].

This study aimed to analyze the implementation period, which is “the transition period [during] which targeted organizational members ideally become increasingly skillful, consistent, and committed in their use of an innovation” [23]. Considering that the proposed innovation (the implementation of a protocol for interaction between the hospital [HEAPN] and the OPO [Programa Estadual de Transplantes]), came from an outsider organization, the assimilation process was assumed to be a crucial step. Assimilation is defined as an organizational process that 1. begins when organizational decision-makers first become aware of an evidence-based health care innovation (EBHI), 2. can lead to the adoption of the EBHI, and 3. may culminate in the EBHI’s routinization or institutionalization by adopter organizations [24].

Studies have been published to identify particular factors that may influence the implementation phase and stakeholder involvement, management of the change process,

championship behavior, and administrative and managerial support, and the most relevant innovation attributes recently have been described [25]. A qualitative analysis would be an elucidating tool for identification of these factors in our project.

After involvement of the TMT and their assimilation with subsequent support behavior, the death referral protocol has been started. The interaction between hospitals' TMTs and the local IHC teams acting as middle managers in this scenario possibly influenced positively the implementation process. TMTs may increase middle managers' commitment in many ways, such as by directly conveying to them that innovation implementation is an organizational priority, allocating implementation policies and practices, and even encouraging middle managers to leverage performance reviews and human resources to achieve innovation implementation [26].

In fact, the role of the IHCs as middle managers in this innovation should be better understood, since these professionals, as nurses, social workers, and intensive care unit doctors, have a strategic location between the TMT and frontline employees. Since the IHCs are the specialized donation professionals, their role in implementation with sensibilization and diffusion of the innovation may be considered as fundamental [27].

From what we know, our study is the first to document the implementation of a regional system exclusively oriented toward cornea recovery in Brazil, reporting a complex interaction between managers. The approach and analysis from the innovation implementation point of view is also original and can bring ideas to other projects within the organ and tissue donation field, but also for the health care system as a whole.

## CONCLUSION

From our analysis of the data obtained from hospital and OPO administrative registers and comparison of these data with previous articles published, it is clear that a better result could be obtained. First of all, only 63.5% of all deaths were referred to the OPO, which limited the number of PTDs available for screening and assessment. In addition, logistical problems such as lack of infrastructure at the hospital or lack of a specialized professional also played an important role in the final results.

This study contributed to the estimation of PTDs in our population, since no data were available until now in the Rio de Janeiro State OPO area. At HEAPN, there may have been up to 693 PTDs (that would be eligible in theory for donation), and with a performance improvement, it may be possible to reach up to 300 cornea donors every year.

An integrated system with specific policies and practices for cornea donation is critical to achieving satisfactory results. In Rio de Janeiro, the engagement of all stakeholders was possible due to a solid strategic plan from top managers and an efficient execution from middle managers.

Further studies will be needed to measure the implementation effectiveness and improve the number of cornea and tissue donors, but this study can bring an optimistic vision for the health care and transplant system in our region.

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