# Hospital Cornea Retrieval Programme in a startup eye bank – A retrospective analysis and lessons learned

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**Purpose:** This study aimed to share our experience in the hospital cornea retrieval program as a new eye bank. **Methods:** This was a retrospective study conducted in a tertiary care institute from August 26, 2019 to March 22, 2020. The medical and eye bank records were analyzed for hospital mortality, mortuary records, and donors approached. The corneal collection was divided between Voluntary (received from voluntary calls), HCRP (cornea received from hospital deaths), and Medico-Legal Cases (received from MLC deaths in hospital) to see the trend of donation and utilization over time. **Results:** During the study period, 154 corneas (77 pairs) were collected. The HCRP provided a major source of corneas 58.4% (90 corneas) as compared to voluntary 19.5% (30 corneas) and MLC 22.1%(34 corneas). There were younger tissues in MLC than HCRP donors, and older tissues in Voluntary donors, and the difference was statistically significant. There was no significant difference in the quality of optical grade tissues and the utilization of corneas for transplants between the three groups. Post hoc analysis showed more non-optical tissues in the voluntary donations ($P = 0.004$), maximum donors with medical contraindications in the HCRP group ($P = 0.001$), and time-lapse in corneal retrieval in MLC cases ($P = 0.0001$). Of these 154 corneas, 78 (50.6%) were assessed as suitable for transplantation, of which 59 (75.6%) tissues were optical grade tissues. The overall utilization was 39.6%. **Conclusion:** HCRP is indeed challenging for a new eye bank, but proper understanding and implementing strategies may help for good utilization of tissues.

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Although significant advancements have been made in eye banking and corneal transplant surgery, the number of corneal donations still falls short of India's demand.[1] There are 740 eye banks and collection centers in India, but the corneal procurement was 56,000 corneas in 2018-19, and 27,016 transplants were done in that same year (EBAI unpublished data). There is still a need of 277,000 donor corneas every year to do 1 lakh corneal transplant to treat corneal blindness.[2] This demand for donor corneas comprises less than 1% of total deaths in a year.

India has an opt-in system where an obligation to obtain next of kin's consent, is a significant hurdle to corneal donation.[3,4] Voluntary donation and Hospital Cornea Retrieval Programme (HCRP) are the two ways of recovering donor cornea. Voluntary eye donation is a sort of social responsibility of the citizen towards people with corneal blindness. Unfortunately, despite many efforts by the National Programme of Control of Blindness (NPCB), Eye bank association of India (EBAI) and many Non-Government Organizations, there has not been much improvement in the voluntary donation.[5]

On the other hand, in HCRP, a professionally trained grief counselor (eye donation counselor or EDC) motivates a deceased's family in the hospital setting toward the donation of the diseased eyes. HCRP has multiple advantages. In India, a significant proportion of the deaths occur in an in-patient setting, which provides the advantage of easy accessibility of potential donors. High to medium mortality hospitals have a high potential for eye donors, and if effectively counseled by the EDCs, can convert into a corneal donation.[5] Other advantages include readily available medical history, availability of younger tissues, lesser time spent in corneal retrieval, and cost-effectiveness. Therefore, much emphasis is being given to eye banks to follow this strategy to increase corneal donation. The experience of major eye banks suggests that HCRP accounts for a large proportion of tissue collection. Further, tissue utilization was found to be higher in tissues collected under this scheme.[6,7]

However, EDC plays a pivotal role in the HCRP program, and studies have demonstrated that EDC's counseling skills are directly linked to the consent rate irrespective of the community awareness of eye donation.[8,9]

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The Rishikesh Eye Bank (REB) was established within the premises of All India Institute of Medical Sciences, Rishikesh, in 2019. The eye bank's genesis was the result of a collaborating agreement between All India Institute of Medical Sciences, Rishikesh, LV Prasad Eye Institute (LVPEI), Hyderabad as the technical collaborator, The Hans Foundation (THF) and Tata Trust as the financial collaborator. This agreement is for three years, following which the entire operations will be under the direct control of the All India Institute of Medical Sciences, Rishikesh. The eye bank and corneal transplant services were inaugurated on August 20, 2019, after receiving the Human organ transplant act (HOTA) certificate from the state health department. The eye bank has a medical director (cornea specialist) and four trained eye donation counselors cum technician who joined the eye bank after being trained at Ramayamma International Eye Bank in LVPEI. The eye bank collects corneas through voluntary and HCRP, with greater emphasis on HCRP.

In this manuscript, we share our experience with the HCRP program. We believe that our experience as a new eye bank in starting HCRP and the challenges we faced might help the other eye banks implement it.

## Methods

We analyzed the eye bank records of all donors approached by the EDCs for eye donation between 26th August 2019 and 22nd March 2020. As a standard operating procedure at REB, EDCs captures following details in a register: the name and relation of the informant, the ward where the death happened, cause of death, outcome of grief counseling, the reason for denial to donate if the next of kin is not willing to donate as well as the reason for not approaching for grief counseling and donation.

For ascertaining the total number of deaths in the hospital during the study period, we took the help of the medical record department of the AIIMS, Rishikesh, which maintains data of every single death. We also reviewed the forensic department's records to determine the number of dead bodies brought there for the postmortem. This data helped us in estimating the number of deaths missed by EDC's.

AIIMS Rishikesh is a 1000 bedded multispecialty hospital with a separate trauma, emergency, High Dependency Unit (HDU), Intensive Care Unit (ICU), Cardiac Care Unit (CCU) and separate wards for all specialties. During the study period, the average number of hospital deaths ranged between 4 and 8 per day. The four EDC/technicians are posted around the clock to provide 7-day, the postgraduate ophthalmology resident supports 24 hours' coverage and on eye donation call. The eye bank has two dedicated phones (one mobile and one landline).

To facilitate eye donation in medico-legal cases (MLC), we obtained the necessary permission from the district police department (Senior Superintendent of Police), and copies of this were distributed to all the police chowkis of our district. With the help of the faculty, residents, and the EDC's of our department, an eye donation awareness campaign was started in the hospital amongst the doctors, residents, and nursing officers to help in the HCRP for eye donation.

The study was approved by the institute's ethics committee and conformed to the Declaration of Helsinki's guidelines.

After obtaining consent from the next of kin, corneoscleral rim excision was performed in all cases unless the deceased had contraindication for the human use of corneas. In a later situation, whole eyeball removal was performed so that the eyes can be used for education or research after taking consent from the family. We adopted the policy of approaching every deceased family without considering utilization even to those having contraindication for human use for the sole purpose of using the opportunity for increasing awareness among the public, sensitize our hospital staff towards eye donation, and facilitate resident training. The only exception to this rule was the deceased with known seropositivity for hepatitis B, C, HIV, syphilis, and deceased with mutilated eyes. The list of contraindicated cases not suitable for transplant was followed as per the guidelines of NPCB.[10]

The Potential donors were defined as the deceased, where the corneal donation will be used for a corneal transplant.

Non-potential donors were defined as the deceased where, even if corneas are donated, the tissue will not be used for transplant.

Approached means that the EDC's went to the families of the deceased for eye donation counseling.

The data were also analyzed for donations between Voluntary (received from voluntary calls), HCRP (cornea received from hospital deaths), and Medico-Legal Cases (received from MLC deaths in hospital) to see the trend of donation and utilization over time amongst the groups.

The quality of tissues was classified as *optical* if the endothelial counts were ≥2200 cells/mm$^2$, *non-optical* if endothelial counts were <2200 for corneoscleral buttons and *eyeballs* in case of enucleation.

Status of tissue was classified as *useful* if it can be used for transplant, *Contraindicated* if it cannot be used for transplant, and *Time-lapse* if the tissue could not be utilized due to delay in retrieving the corneas more than 12 hours.

Utilization of the tissues was classified as, *Utilized* if the tissues were used for transplant, *Not Utilized* if the tissues were not used due to contraindication, tissue damage during surgery or expiry of the tissues due to non-availability of patients and *Long term preserved* if the tissue were transferred to glycerol for long term preservation.

### Statistical analysis

The statistical analysis was done in SPSS version 23.0. Normally distributed continuous variables are expressed as mean ± 2SD and categorical variables in percentages. Annova is used to analyze the age distribution between the groups. A Chi-square test was used to analyze the categorical variable. A significance level of 5% and CI of 95% was used as statistical significance. Furthermore, Post hoc analysis was done to compare the difference of means between the groups.

## Results

During the study period (from 26th August 2019 till 22nd March 2020), the eye bank collected 154 corneas (77 pairs). Of these, 134 (80.5%) corneas came from the hospital cornea retrieval program (90 corneas from HCRP donors and 34 corneas from

medico-legal cases donors), and 30 (19.5%) were collected through voluntary donations.

A total of 959 deaths and 246 postmortems were registered in the hospital during this period. The HCRP calls register had 697 eye donation call entries. [Fig. 1]. Of these, 609 (87.3%) contacts with the deceased family members were initiated by EDCs posted on HCRP duties, while 88 (12.6%) calls were made by other staff, including nursing and mortuary staff. A maximum number of calls 269 (38.59%) came from emergency and trauma, 191 (27.4%) from the high dependency unit (HDU), 85 (12.19%) from CCU, 28 (4.0%) from mortuary, 38 (5.45%) from pulmonary medicine ward and 86 (12.34%) from other wards of all specialties.

After an initial assessment, grief counseling was abandoned for 95 (13.6%) cases as these were found to have contraindications for donation (posing health risks for eye bank staff or not being suitable even for education or research like mutilated eyes, positive viral markers, or unknown cause of death). Remaining 602 families were approached by our grief counselors. These included 103 (14.77%) cases who were approached despite having contraindications for corneal transplant for the sole purpose of promoting eye donation in the community. Overall, 499 (71.59%) of cases were identified as potential donors. Sixty-two (10.3%) families consented and 540 (89.7%) refused for donation. The reasons for not agreeing for donations are listed in Table 1. In 295 cases, information on the reason for refusal was missing in the register. The consent rate was 6.9% (17 of 246) among medico-legal cases.

The monthly trends of voluntary, HCRP and MLC donations are shown in Fig. 2. While MLC and voluntary donations showed marginal growth, HCRP showed a decline after December. However, the number of HCRP donations were higher all through compared to voluntary and mortuary donors. [Fig. 2]. The mean age of donors in voluntary, HCRP, and MLC groups was 68.3 ± 15.7, 59.7 ± 14.4, and 43.6 ± 20.3, respectively. The difference in the mean age of donors among the three groups was statistically significant [Table 2]. The analysis of tissue utilization among the three groups did not reveal any statistical difference. The same was true for the quality of tissue [Table 3]. There was no difference in the optical grade tissues in the three groups, but non-optical tissues were more in the voluntary group. There were significantly more contraindicated cases in the HCRP group than the other two groups, and tissues not used due to time lapse were seen only in the MLC group [Table 3].

Of these 154 corneas procured during the study period, 78 (50.6%) were assessed as suitable for transplantation of which 59 tissues were optical grade tissues, and 19 were non-optical grade. Forty-nine of these corneas were used at the AIIMS ophthalmology department for transplantation, and 12 corneas were distributed to other corneal surgeons in the state; 11 tissues were long term preserved in glycerol, and five tissues were not utilized due to cancellation of surgeries and non-availability of patients for transplant. One tissue got damaged during lamellar dissection for endothelial transplant. Besides, the eye bank procured 27 corneas from RIEB, Hyderabad, and all were used for transplantation. Overall, seventy-six corneal transplants (49 REB tissues + 27 RIEB Tissues) were performed in the hospital. The overall utilization of the corneas for this period was 39.6%.

Seventy-six tissues (49.4%) were assessed as not suitable for transplant. The reasons for contraindication were sepsis/septic shock (46 corneas), Disseminated cancer/leukemia (6 corneas), a hemolyzed blood sample (6 corneas), Disseminated tuberculosis (4 corneas), Timelapse (4 corneas), Dementia (2 corneas), Parkinson's disease (2 corneas), Patient on a ventilator

**Table 1: Reason for not donating when approached**

| Reasons for not donating | Number of cases |
|---|---|
| Family not interested (Reasons) | |
| 1. Religious causes | 60 |
| 2. Family not satisfied with hospital treatment | 25 |
| 3. Older generation refused | 03 |
| 4. Family aggressive towards hospital staff | 03 |
| 5. Reasons not mentioned in HCRP Register | 295 |
| Next of kin not available | 154 |
| Total | 540 (89.7%) |

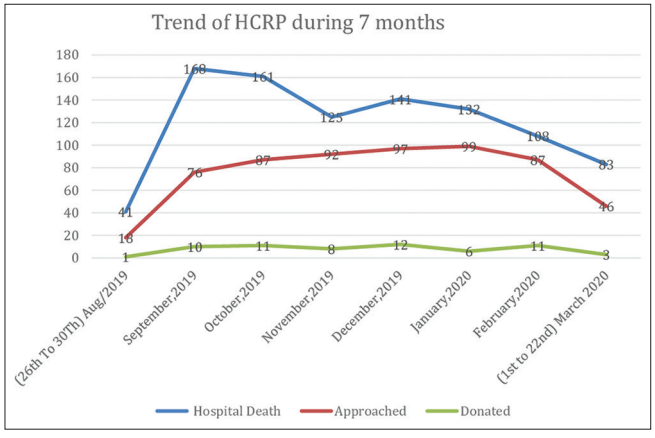


**Figure 1:** Trend of Hospital cornea retrieval programme from 26th Aug 2019 till 22nd Mar 2020

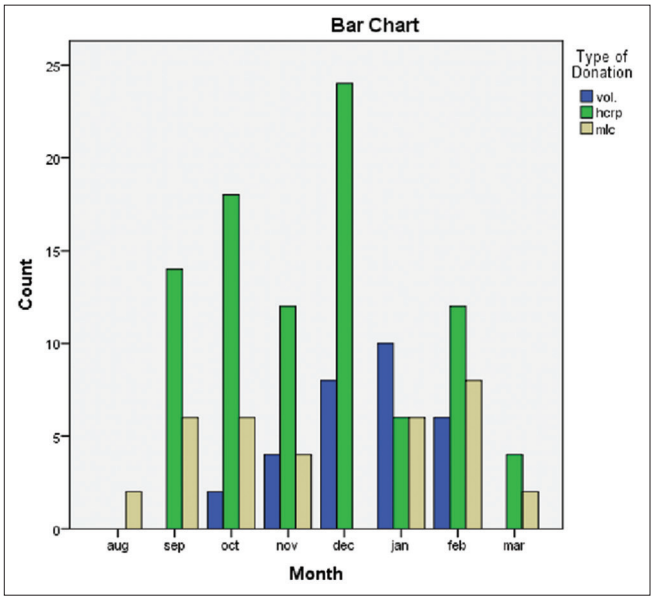


**Figure 2:** Trend of voluntary, HCRP and MLC donations during the study period

**Table 2: Comparisons of the difference of means between the three groups**

| (A) Type of Donation | (B) Type of Donation | Mean difference (A-B) | Std. Error | Sig. | 95% Confidence Interval | |
|---|---|---|---|---|---|---|
| | | | | | Lower Bound | Upper Bound |
| VOLUNTARY | HCRP | 8.6667* | 3.3923 | 0.031 | 0.637 | 16.697 |
| HCRP | MLC | 16.0196* | 3.2392 | 0.000 | 8.352 | 23.687 |
| MLC | VOLUNTARY | -24.6863* | 4.0307 | 0.000 | -34.227 | -15.145 |

*The mean difference is significant at the 0.05 level

**Table 3: Comparison of Quality and utilization of tissues between the three groups**

| | Voluntary *n*=30 | HCRP *n*=90 | MLC *n*=34 | *P** |
|---|---|---|---|---|
| Quality of Tissue | | | | |
| Optical | 16 (53.3%), *P*=0.99 | 46 (51.1%), *P*=0.52 | 20 (58.8%), *P*=0.46 | 0.002 |
| Non Optical | 12 (40.0%), *P*=0.004** | 12 (13.3%), *P*=0.007 | 8 (23.5%), *P*=0.65 | |
| Eye balls | 2 (6.7%), *P*=0.007 | 32 (35.6%), *P*=0.001** | 6 (17.6%), *P*=0.22 | |
| Status of tissue | | | | |
| Useful | 20 (66.7%), *P*=0.05 | 38 (42.2%), *P*=0.01 | 20 (58.8%), *P*=0.28 | <0.01 |
| Contraindicated | 10 (33.3%), *P*=0.10 | 52 (57.8%), *P*=0.001** | 10 (29.4%), *P*=0.021 | |
| Time lapse | 0 (0%), *P*=0.31 | 0 (0%), *P*=0.016 | 4 (11.8%), *P*=0.0001** | |
| Tissue Utilization | | | | |
| Utilized | 14 (46.7%), *P*=0.37 | 33 (36.7%), *P*=0.37 | 14 (41.2%), *P*=0.83 | 0.133 |
| Not Utilized | 12 (40.0%), *P*=0.10 | 54 (60.0%), *P*=0.04 | 16 (47.1%), *P*=0.41 | |
| Long term Preserved | 4 (13.3%), *P*=0.14 | 3 (3.3%), *P*=0.03 | 4 (11.8%), *P*=0.23 | |

Significance of *Chi Square test *P*=0.05, ***Post hoc P*=0.005

for more than 72 hours (2 corneas), Corneal infiltrate (2 corneas), HbsAg positive (2 corneas).

## Discussion

In this article, we are sharing our initial experience with eye banking. While it is easy to set up an eye bank, it is essential to be aware of trends and challenges one faces after eye bank is inaugurated. Our eye bank was started in a dedicated facility with all infrastructure as recommended by the NPCB. The technicians and staff received the necessary training. The eye bank was housed in a large multispecialty hospital. The analysis of 7 month's activities provided the following insight:

**HCRP donors:** Are crucial and provide a major source of corneas. In our case, the number of corneas from the HCRP program was higher than voluntary donation or mortuary donors. We also observed an initial spike in number that rapidly dropped after three months. This could be because of the initial euphoria. Being aware of this, we will reinforce our efforts and provide the necessary thrust. One of the challenges with HCRP is poor consent rate, especially if the family is not happy with the treatment received by the diseased while being hospitalized. This was a significant cause of refusal in our study.

The eye bank employed the policy of motivating contraindicated cases for eye donation to increase awareness, sensitize the medical staff, and provide corneas for resident training. The EDC's motivated 62 deceased families (45 HCRP and 17 MLC), of which 29 (46.77) were useful cases, and 31 (50%) were contraindicated and in 2 donors (3.2%) there was time-lapse so cornea could not be used.

One of the performance indicators of EDC's is the number of useful cases motivated for corneal donation. On interrogation of EDCs to understand the discrepancies between contraindicated cases and useful cases, we were told that they felt tremendous stress while motivating potentially useful cases and were relaxed with no worry about the outcome while counseling cases having contraindication for transplantation. (Personal communication with the EDC's).

Further, lack of motivation after achieving set targets also resulted in relative lethargy, which might have been one of the reasons they missed 27.3% (262) of deaths in the hospital. So it may be a better idea to motivate only useful cases to increase the number of transplantable corneas.

**Mortuary donors:** Our initial experience suggests a poor contribution of mortuary donors. The consent rate (6.9%) was low, but most of the donors were relatively younger. The quality of tissue assessment and suitability for transplantation was also high in this category. The low consent rate could be great emotional shock and grief to the family members from untimed death compared to pathological death. In contrast, a study by Acharya *et al*.[8] did not find any statistical difference in the consent rate for eye donation between pathological and accidental deaths

Nevertheless, another challenge with mortuary donors is the prolonged wait time for permissions from the post mortem medical officer and police, which adversely affects the quality and suitability of donor tissues. The situation is worst if a case has the potential of media attention. In our initial experience, it was easier to convince the deceased's family to get consent for donation than to take consent from the police and the forensic expert. There was always some degree of confusion regarding who should sign the consent form first. Sharma *et al*.[11] also showed in their study that there was a significantly higher death to preservation time in HCRP donations than voluntary donation due to time-consuming medico-legal formalities.

This situation wherein an EDC and family are ready for eye donation, but the police and forensic department are reluctant to provide necessary support is very disheartening and discouraging.

**Voluntary donors**: Awareness about eye or organ donation in a community is essential but will not guarantee that the public will do their part. Like many other studies and experiences of other eye banks (unpublished data), awareness of eye donation in our country is relatively low. Most of the donors are relatively old age. Contrary to other experiences, we observed that 50% of corneas were of good quality, and 66% were evaluated as suitable.

**Contraindications:** Major cause of rejection of corneal tissues for in-hospital transplant deaths is medical contraindications, and septicemia is the most common cause for rejection.[12] Of 959 deaths in our hospital, 414 (43.16%) septicemia were reported as a primary or secondary cause of death. Of 62 donations through HCRP, 23 (37.09%) were rejected due to septicemia, even though they were good quality tissues. Gustave *et al*.[13] concluded that there are no clear cut signs except positive blood culture, correlating with a higher likelihood of septicemia. The signs designated to sepsis,[14] mostly represent the physiological response known to all types of shock and not just septic shock. It is believed that tissues retrieved from septicemic patients when transplanted may cause endophthalmitis, although the evidence in literature is week.[15-17] Studies by Nagaraja *et al*.[18] and Mathur *et al*.[19] have shown no correlation between organisms causing septicemia, and that grew in cultures of corneoscleral donor buttons of the deceased. Spelsberg *et al*.[20] transplanted 91 donor corneas from donors classified as having sepsis and showed 92% clear graft survival after two years in this group. The guidelines for contraindication for corneal transplant need to be revised to prevent tissue wastage in countries like ours, increasing corneal donation.

## Conclusion

Organ/Tissue donation does not happen until we make an effort to happen. Hospital cornea retrieval program is such an effort, focusing on motivation and grief counseling of families in hospital-based deaths. The challenges in HCRP for a new eye bank could be easily overcome by properly implementing strategies, sensitizing the hospital staff, police, and doctors towards their responsibilities. Also, the medico-legal formalities should be liberalized and simplified to promote the noble cause of corneal donation.

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### Conflicts of interest

There are no conflicts of interest.

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