

## Upgradation and modernization of eye banking services: Integrating tradition with innovative policies and current best practices

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**Purpose:** The purpose of this study is to review the history and evolution of the National Eye Bank (NEB) and analyze the impact over the years and report the outcome of the invested resources. **Methods:** Review of archival material, records, project reports, policy and procedures' manuals, and publications was done. Descriptive and analytical processing of data obtained was undertaken. Parameters evaluated included total collection, transplantation, utilization rates of donor cornea, changing trends over time in terms of numbers and duration of recipients waiting, impactful research translated into changes in standard operating protocols, new facilities, and subsequent effects on numbers or quality assurance measures and overview of major achievements. Periodic situational analysis with contextual relevance and interpretation of outcomes was done pertaining to national goals and international standards. **Results:** The NEB and cornea services have played a key leadership role in furthering the development of eye banking and corneal transplantation services. The contribution extends beyond routine patient care to education, training, generation of resources, advocacy, and policymaking. In quantifiable terms, the overall performance has steadily increased over the years. Major contributions include training of doctors, eye bank staff and corneal surgeons, introduction of innovative techniques for corneal transplantation, setting of national standards for eye banking and provision of preservation media, customized corneal, and ocular surface cell replacement therapy in collaboration with other departments and institutes. **Conclusion:** The eye banking and corneal transplantation facilities have evolved with time providing quality services, modernized as appropriate with updated knowledge and incorporating technological advances supported by the systematic evidence-based approach.

**Key words:** Cornea, donation, eye bank, transplant

The National Eye Bank (NEB) was established in 1965 in the premises of All India Institute of Medical Sciences (AIIMS), New Delhi and linked with the Department of Ophthalmology headed by Professor L. P. Agarwal. Dr. Madan Mohan was entrusted with the responsibility of setting up the facility for eye banking and corneal transplantation. Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS, New Delhi was founded on March 10, 1967, and on the occasion of its 50<sup>th</sup> year of establishment; the journey of the corneal surgeons associated with the eye banking facilities at the center over the years is worth reviewing and sharing. The center is the apex institute for ophthalmic care under the National Program for Control of Blindness (NPCB) and has always served as a role model both nationally and internationally. The eye bank has grown *pari passu* with the hospital and is well recognized as a valuable public funded national resource. This paper evaluates its progress over the years and presents the major achievements in terms of measurable outcomes.

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## Methods

The study was conducted in accordance with the tenets of the Declaration of Helsinki. An assessment of resources available for study was made and possible sources of information were identified. Requisite administrative approval was obtained for the study of hospital records, files, and documents. Archives of information accessible were accessed including information gathered from retired personnel. An online literature search was made for published studies, and library repository of thesis work scanned for relevant research work. The online literature search was done using keywords such as eye banking, donor corneas, awareness, keratoplasty, limbal stem cell transplant, amniotic membrane, preservation media, NEB, and India. Data presented in annual reports and meetings was reviewed. Information was distilled to extract relevant material to assess the progress over time in terms of total collection, transplantation, any quality assurance measures or policy changes, new facilities introduced or application

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of technological advances and upgradation of medical standards.

## Results and Discussion

Started from a small room at the Ophthalmology Department the NEB at Dr. Rajendra Prasad Centre for Ophthalmic Sciences has emerged as one of the most well equipped and developed eye banks of the country keeping pace with the emerging technologies to develop best practices. The eye banking services have evolved with periodic inputs from community and hospital-based studies including thesis research work and evidence-based analysis which has helped upgradation. The various components of this growth and development are presented as follows.

### Collection and utilization

The progress of the eye bank in terms of collection of donor cornea has seen steady increase with time. Performance analysis at different intervals was reported to show an increase in the utilization rates with improved usage of nonoptical grade tissues.<sup>[1]</sup> This was attributed not only to the increasing number of therapeutic and tectonic keratoplasty procedures but also to anterior lamellar and keratoprosthesis surgeries.

A comparison of NEB statistics with compiled data for India reveals a continuous trend in improved cornea collection and utilization [Figs. 1 and 2] and Table 1. This can be attributed to a targeted approach and dedication of those involved in creating awareness and those who are responsible for efficiency in tissue processing and distribution.

### Indications for corneal transplantation

A review<sup>[2]</sup> of eye bank records for indications for keratoplasty at the center from June 1997 to November 2003 was reported showing the leading indications as follows: corneal scarring (38.03%) and acute infectious keratitis followed

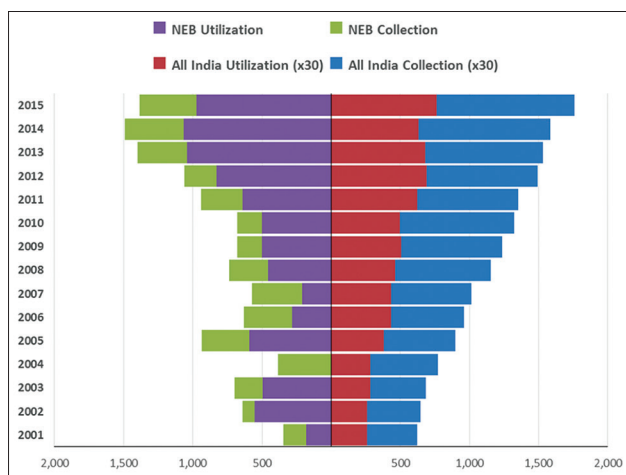
by regrafts, aphakic bullous keratopathy, pseudophakic bullous keratopathy, and corneal dystrophy. Bilateral corneal blindness<sup>[3]</sup> is a significant public health problem and needs advocacy at the national level. Study of clinical profile of patients presenting with bilateral corneal blindness reported that corneal infections (63.6%) are the most common indication for keratoplasty. The infections tend to be more in the rural population and lower socioeconomic strata. The most common indication for pediatric keratoplasty<sup>[4]</sup> was infectious keratitis, followed by congenital glaucoma and trauma. Graft failure was seen in 18.4%, and corneal infection was the most common cause (50%) of graft failure.

The techniques of keratoplasty employed have demonstrated a shift towards anterior lamellar surgeries and Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK). These component customized surgeries<sup>[5-8]</sup> dedicated to different layers of the cornea have lesser complications as compared to open-sky procedures, hence are gaining popularity with the advancing technology.

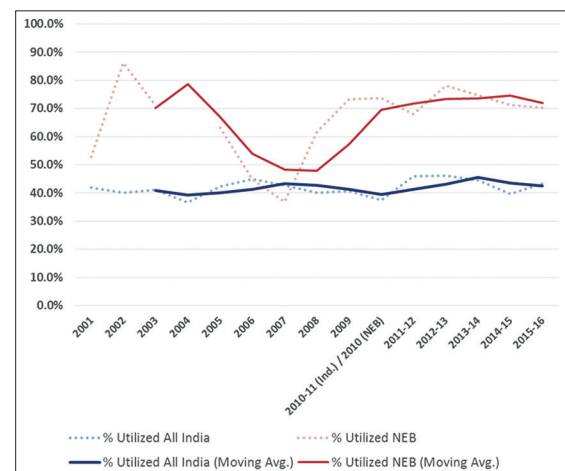
To meet the challenges of eye banking in the developing countries experience shows the need of choosing recipients selectively avoiding surgery in cases with high risk of functional and anatomical failure when the fellow eye is normal.<sup>[9]</sup> The aim is to prioritize patients and fulfill the demand effectively.

### Tissue harvesting and processing

The eye bank processing involves various quality control procedures such as harvesting, transportation, processing, storage, and ensuring availability to transplant surgeons. Throughout this, it is of utmost importance to take adequate measures for infection control and maintenance of cold chain. Periodic evaluation has helped us to improve on our techniques to do so. These procedures are carried out adhering to the guidelines issued by the NPCB. The NPCB standards are a useful document providing guidelines for best practices for eye banking in the country. Quality control



**Figure 1:** The annual collection and utilization of corneas in India and in the National Eye Bank, 2001–2015. The numbers for cornea collection and utilization for 'All India' have been scaled down by a factor of 30 to enable better side-by-side comparison of utilization proportions each year against the National Eye Bank. The total length of each bar from the zero on x axis represents the collection or utilization and the bars are overlaid (not stacked). The 'All India' figures also include NEB collection and utilization



**Figure 2:** The annual utilization proportion of corneas in India and in the National Eye Bank, 2001–2015. Three year moving averages have been computed to smoothen year to year variations in corneal utilization proportion. While the 'All India' utilization is steady between 40% and 50%, the utilization at National Eye Bank has shown consistent increase since 2007 and is currently around 70%

**Table 1: The annual collection and utilization of corneas in India and in the National Eye Bank, 2001–2015**

Year	All India		NEB	
	All India collection (x30)	All India utilization (x30)	NEB collection	NEB utilization
2001	623.9	260.7	344	182
2002	645.0666667	257.8666667	643	554
2003	683.8	280.8666667	698	496
2004	773.2666667	283.4666667	383	
2005	895.5	378.9666667	938	592
2006	961.9	432.5	633	283
2007	1011.766667	432.3	572	211
2008	1152.966667	462.9	739	456
2009	1236.766667	503.3666667	680	498
2010	1322.533333	494.5666667	677	499
2011	1353.9	622.7666667	941	640
2012	1493.533333	687.7333333	1062	830
2013	1532.3	680.9666667	1398	1043
2014	1583.666667	629.5666667	1493	1064
2015	1758.6	761.9333333	1386	973

NEB: National Eye Bank

is of paramount importance for successful eye banking and corneal transplantation and adherence to standards is recommended.

During retrieval of donor tissue, it is essential to ensure adequate asepsis as any breach can have grave complications, one such being postkeratoplasty infections. A series of cases of postkeratoplasty infection<sup>[10]</sup> were studied and highlighted the consequences of resistant species of microorganisms surviving in the commonly used preservation media, i.e., McCarey–Kaufman (MK) media. It emphasized the need to culture the donor scleral rim at the time of transplant. It is advisable to bring the donor tissue to room temperature before transplant and to maintain strict postoperative protocol for through evaluation to pick up early signs of graft infection.

Several studies have been done to evaluate different decontamination protocols to minimize risk of infections transmitted from donor cornea by different antimicrobial agents so as to compare their efficacy.<sup>[11]</sup> Noteworthy findings include that saline wash leads to a 20% decrease in microbial load, further instillation of 1% povidone-iodine for 3 min is most effective compared to the application of antibiotics such as ciprofloxacin, combination of ceftazolin and amikacin, Neosporin and gentamycin. Use of 5% povidone-iodine and amikacin was found to be better than 1% povidone-iodine and gentamicin but still not adequate to eliminate all Gram-negative organisms.<sup>[12]</sup> Further addition of gatifloxacin 0.3% eye drops help reduce the residual load of organisms. Multi-drug resistant *Pseudomonas* sp. were found sensitive to polymyxin B.<sup>[13,14]</sup> The combined use of povidone-iodine (5%) and antibiotic eye drops effectively decreases the microbial positivity of corneoscleral rims after *in situ* retrieval in hospital mortuaries.<sup>[14]</sup> These studies have allowed us to modify our protocols for infection control and decrease the chances of postgraft infection related to the donor tissue.

Ecological factors require due consideration when considering corneal retrieval. Adverse environmental

conditions such as high temperature and humidity may increase chances of infection postkeratoplasty.<sup>[15]</sup>

Over the past decade, we have shifted our approach from whole globe retrieval to corneoscleral rim excision (*in situ*). As regards to the actual technique of eye donation, this shift has helped decrease the processing and death to preservation time thus ensuring better quality tissues. Furthermore, this technique appeared to have better acceptability in the society. Quality assessment<sup>[16]</sup> in terms of visual gain and endothelial cell count was done comparing whole globe removal versus *in situ* excision of corneoscleral rim. The parameters assessed, suggested that visual function, graft clarity, and endothelial cell count were comparable at the end of 3 months. There were only two cases of postkeratoplasty infection reported from *in situ* excision group.

Another area of concern is the timeline. The following time intervals are important to document and are important in terms of quality control of donor tissue.

#### Death recovery interval

Refers to the duration in hours between the time the individual was declared dead to the time at which the donor tissue was retrieved. A preferred death to recovery time is <12 h. This is so as the tissue retrieved is more suitable for transplant use if retrieved early and there are less chances of infection.<sup>[17]</sup> Another point to be considered here is cornea retrieval from ventilated patients. A research work from our center highlighted that corneas can even be retrieved from those on ventilatory support for >72 h provided corneas are in good clinical condition.<sup>[18]</sup> This emphasizes the need for good eye care practices in Intensive Care Units. Eye care may not be given significance when in such a setting where saving the life is primary concern thus the concerned staff at the time of retrieval needs to assess the situation carefully before considering for retrieval.

#### Death preservation time

It refers to the duration in hours between the time the individual was declared dead to the time the retrieved tissue

was preserved. This again is an important parameter as shorter the duration less are the chances of donor tissue induced infection<sup>[17]</sup> and better is the quality of the tissue.

### Preservation surgery interval

It refers to the duration in hours the tissue is maintained in the preservation media. A short duration between preservation to utilization is advantageous as even when stored within the media for long the optical quality of the tissue tends to degrade. Best is to use immediately if possible or within 12 h but 48–72 h is acceptable.

### Hospital cornea retrieval program

A prospective study<sup>[19]</sup> was done evaluating the factors that affect the eye donation in postmortem cases. Potential donors were identified and next of kin were counseled and interviewed based on a set format by trained counselors. The responses were noted in terms of awareness and willingness to donate. It was noted that only 55.4% of the people were actually aware of eye donation and only 44.3% out of these volunteered to donate. Factors such as previous knowledge, literacy, and socioeconomic status had no influence on donation. The study concluded and highlighted the importance of active counseling by trained and dedicated group of individuals to increase eye donation. This data facilitated the Delhi Centralized hospital cornea retrieval program (HCRP) project with SightLife to support the provision of eye donation counselors.<sup>[20]</sup> A retrospective<sup>[21]</sup> performance analysis of efforts to promote corneal donation was also done. It assessed the “lost opportunity cases” which was noted to be 78%, thus decreasing effective corneal donation to 1.9% among the potential donors. Delay in conducting autopsy was a major cause. These alarming percentages suggest a need to reassess the approach and have effective measures to promote tissue donation.

This has encouraged running of awareness programs such as the eye donation walks and fortnight celebrations, rewarding and acknowledging the donor families, educating and counseling families of inpatient or outdoor patients awaiting keratoplasty and holding community-based awareness programs. There needs to be good coordination between the medical officers, nurses health personnel, counselors, technicians, forensic experts, and the legal system for an effective implementation of HCRP and to decrease the number of lost potential donors

### Record keeping

Record keeping is an essential part of an eye bank. A good system enables efficient workflow and facilitates usage of the data for operational research. It is important to maintain information such as patients registered for keratoplasty, the type of keratoplasty they are registered for and the priority list. Complete demographic information with contact details is maintained. Next is the data of the donated tissues received, whether it was voluntary donation or by active counseling. Complete donor details with demographic data, cause of death, time of death and recent investigations should be maintained. These are important to decide for their adequate utilization and to trace back in case of any postgraft infections. Finally, data should be maintained about the transplant procedures done. This helps us to understand utilization trends and plan better management protocols.

The corneal transplant registry was established to help evaluation of outcomes of corneal transplant services.<sup>[22]</sup> It helps identifying modifiable factors and understand changing trends of corneal procedures and need to improvise them. The study revealed a few aspects: The percentage of the retrieved corneas utilized was 71.7%, primary failure rate was 4.25, and secondary was 7.5%. The overall results as documented by our graft registry were comparable to those of developed nations such as the UK and Australia at 1 year. This form of assessment can formulate better protocols for eye donation and their efficient use to ensure favorable outcomes. The graft registry also helps understand the visual disability burden prevalent in the society.

### Reporting

The NEB maintains records of any adverse events reported following keratoplasty which can be attributed to the donor tissue or to the tissue retrieval techniques. This is important so as to prevent another similar complication due to transplant of the mate donor tissue or in case it has been transplanted to inform the surgeon for close vigilance.

### Legal compliance

The Transplantation of Human Organs Act was passed by Parliament in India in 1994 and became operational after notification in the official Gazette. This legislation was passed to control the illegal sale and trafficking of organs particularly kidneys, but the text did mention that “eyes and ears can be harvested anywhere by a registered medical practitioner” and that the “cornea transplant Act of 1983 was hereby repealed.” This brought eye donation and corneal transplantation under the ambit of the new act. There were some perceived legal hurdles for promotion of eye donation and transplantation such as requirement of a registered medical practitioner, criteria for transplantation centers including need for perfusionist, blood bank, Intensive Care Unit etc.

Feedback was provided by experts from NEB and Eye Bank Association of India (EBAI) for processing requests for amendment. The Act was amended to include tissues in 2011 and rules published in the National Gazette as Transplantation of Human Organs and Tissues Rules 2014.<sup>[23]</sup> Cornea was hereby clarified as a tissue and not to be treated as an organ; consent for donation as legal next of kin was extended to include more relatives and trained technicians were authorized to harvest corneas. The additional supportive aspects include a provision for mandatory required request in case of all intensive care mortality and advocacy for availability of transplant coordinators and eye donation counselors to facilitate the HCRP.

The National Organ and Tissue Transplant Organization has been established by the central government under the ambit of the law and will operate in collaboration with Regional and State Organ and Tissue Transplant Organizations. Overall, the legal framework in the country is conducive to facilitate the activities for eye donation and corneal transplantation work.

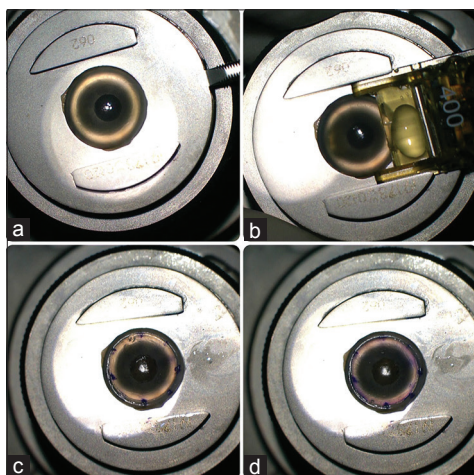
### Advocacy

A population-based corneal opacity rural epidemiological<sup>[24]</sup> study was done to assess vision related quality of life (VR QoL) in rural North Indian population. VR QoL was impaired in patients with corneal disease more so in those with corneal

blindness. This population-based study provides new insights into the prevalence, risk factors, and causes of corneal blindness and morbidity across all age groups in a rural Indian population.

#### Financial support

NEB receives its financial support under NPCB and is a government funded organization with financial supplementation by extramural projects.



**Figure 3:** (a) Positioning corneal button in an artificial anterior chamber. (b) Cutting the cornea with an automated microkeratome with 400  $\mu$  blade on surgeon request. (c) Marking the edge of cut stromal bed. (d) Repositioned anterior cap before replacing in media for distribution

#### Revision of manpower

The workforce employed at the eye bank is a group of trained laboratory technicians, counselors and transplant coordinators led by two chairmen and two medical directors. The counselors are graduates and are trained under and NPCB with support from nonprofit organization such as ORBIS, SightLife etc., initially for a period of 1 month and then periodic assessments and skill enhancing sessions. Similar programs exist for technicians and transplant coordinators

#### Upgradation of resources

Initiation of computer-based entry for eye bank data provided easy accessibility. The online pledging system introduced helped increase awareness by educating the general population.

#### Technological advancements

Apart from the corneal tissue itself another important area is the ocular surface and its reconstruction (OSR). The NEB has had significant role in manufacture, storage, and distribution of amniotic membranes with help from the stem cell facility at AIIMS. Amniotic membrane grafting (AMG) has wide role in OSR in terms of acute chemical injury,<sup>[25-27]</sup> acute Steven-Johnson syndrome,<sup>[28]</sup> as a substrate for cultivation of stem cells and limbal epithelial cell transplantation procedures.<sup>[29,30]</sup>

#### Corneal preservation

Facility for providing MK-medium to all government eye banks exists in the Department of Ocular Pharmacology with support from NPCB. The use of different media to increase the shelf life of corneal buttons received at the eye bank includes the practice of recovering tissues in MK-medium

**Table 2: Innovations and strategies adopted by the National Eye Bank over the years to address the challenge of corneal blindness**

Challenge faced	Strategies and interventions adopted
Availability of donor tissue	Networking with eye donation centers Hospital-based cornea retrieval program Awareness generation activities in community, educational institutes, etc. Initiation of a toll-free number for potential donors to call in Adoption of <i>in situ</i> corneoscleral rim excision
Storage and preservation of tissue	In-house facilities for preparation and distribution of MK preservation media Research to identify use of glycerol as long-term preservation medium Supporting fellow eye banks through supply of MK media
Utilization of donated tissue	Adoption of lamellar keratoplasty and Descemet's stripping automated endothelial keratoplasty techniques
Infective complications	Development of protocols for ensuring corneal preservation media sterility and disinfection of donor globe and corneas after collection
Graft failure	Inclusion of fellow eye status in assessing priority for keratoplasty and risk of functional and anatomical failure
Shortage of skilled surgeons in India	Trainings for surgeons in keratoplasty
Pushing the frontiers in eye banking research	Exploring use of amniotic membrane transplantation Umbilical cord serum Limbal stem cell transplantation
Operational research in eye banking	Corneal transplant registry established Data analyzed regularly to assess current situation and used to identify required corrective strategies and interventions

with subsequent transfer to intermediate storage media.<sup>[31,32]</sup> Tissue preservation in anhydrous glycerol at  $-80^{\circ}\text{C}$  was found to be effective to maintain sterility of the tissue, corneal thickness, better optical transparency, tensile strength, and ultrastructural features.<sup>[32]</sup>

### Collaborations and partnerships

The NEB has international and national partners such as World Health Organization and SightLife and EBAI. The NEB also works along with other eye care hospitals and eye donation centers and helps provide facilities to other government centers willing to practice HCRP the instruments, transport media and storage media free-off cost. The cornea transplant services at our center have the provision to offer pre-cut tissues to other ophthalmic government institutions [Fig. 3]. Tissues are prepared with automated microkeratome 350  $\mu$  blade if cornea thicker than 600  $\mu$ , 300  $\mu$  if less or as per surgeon request.

### Future prospects

Currently the option of corneal substitutes and tissue bio-engineering in terms of endothelial cell culture are being explored and may prove useful in cases of corneal endothelial dysfunction.<sup>[33,34]</sup>

### Conclusion

The NEB has played a leadership role in development of eye bank services with influence on policy planning and development of guidelines and standardized protocols as summarized in Table 2. Impactful interventions for quantitative improvement are hospital cornea retrieval programme (HCRP) and *in situ* corneal excision and for qualitative enhancement of utilization are intermediate storage media and monitoring of death preservation time.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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