

ALLOCATION CRITERIA FOR CORNEAS

Cornea transplant is supported by cornea donation from a deceased donor. Recipient allocation needs to be standardized. The allocation of organs/tissues is a complex process, influenced by a number of factors including medical urgency, capacity to best benefit, donor/recipient matching and logistical factors. Following facts related to cornea transplantation needs to be kept in mind while making a standard policy for allocation:

CERTAIN FACTS

1. There is disparity between number of recipients requiring transplant and the availability of corneas suitable for transplantation.
2. Some patients need corneal transplant on priority basis because of their medical condition, as delay in transplant may lead to considerable morbidity.
3. Corneas not suitable for transplantation for optical purpose may sometimes be useful for emergency therapeutic or tectonic use or for anterior lamellar keratoplasty, but it is not necessary for all such corneas to be used as there may not be a suitable patient for such purpose at the appropriate place or time.

REGISTRATION, WAIT LISTING and SCORING of PATIENTS for CORNEA TRANSPLANT

1. Patient can be of any age or gender.
2. Patient should be a case of corneal disease treatable by keratoplasty.
3. Patient should be an Indian National until the local backlog is cleared as per THOTA distribution policy in letter and spirit (refer page para).
4. Each patient is to be registered in ONE hospital which is registered for corneal transplant under THOTA.
5. Patients' complete details including multiple IDs are to be put by the respective hospital through an online registration form on www.notto.gov.in.
6. One recipient can be registered ONLY IN ONE HOSPITAL, though he/she can change the hospital at any stage and his allocation scoring will not change. Recognition of the patient with new hospital will be applicable only after one month of change in hospital.
7. Status of patient must be updated by the registering hospital EVERY YEAR into active, inactive i.e. still to remain on waiting list or to be removed due to any reason.
8. Patients should be registered by a corneal transplant surgeon through a registered transplant centre.
9. Non optical grade corneas are generally more easily available and often do not get transplanted so any demand for such corneas should be encouraged as they can be utilized for anterior lamellar keratoplasty and emergency therapeutic or tectonic keratoplasty.

10. SCORING SYSTEM FOR PRIORITIZATION IN ALLOCATION OF OPTICAL GRADE TRANSPLANTABLE CORNEA

SN	Criteria for scoring	Points allotted
1	Visual Disability bilateral blindness i.e. BCVA in better eye \leq 3/60 economic blindness i.e. BCVA in better eye \leq 6/60 visual disability i.e. BCVA better eye \leq 6/18	+ 3 + 2 + 1
2	Bullous Keratopathy or endothelial failure such as Fuchs Dystrophy eligible for endothelial keratoplasty with good visual prognosis	+ 3
2	Primary donor failure	+ 4
3	Age of recipient	+ 3 < 6 years + 2 6-12 years +1 12-18 years
4	Associated diseases affecting inferior outcome Healed keratitis with deep vasculatization in \geq 2 quadrants or adherent leucoma Associated with uncontrolled glaucoma Expected Poor visual potential due to posterior segment pathology/ Squint	- 2 - 2 - 2
5	Emergency Graft with potential for good prognosis* Impending perforation Perforation Progressive infective keratitis *If poor prognosis then non optical grade cornea can be directly utilized without waiting	+ 4

BROAD PRINCIPLES FOR ALLOCATION

Considering the above facts, donated corneas should be used in a way that balances medical need of patient with the likelihood of successful transplantation outcome, taking into account the following general criteria in considering potential recipient for allocation of organs.

1. No transplantable cornea should go waste for the want of best allocation.
2. Transplantable optical grade corneas must be allocated in a timely manner so that they can be suitably transplanted. Non optical grade corneas cleared for anterior lamellar, therapeutic or tectonic keratoplasty should be matched with best suited recipient and utilized as best possible. General public and donor families should be made aware that sometimes these corneas may not be utilized due to various reasons. Eye Banks should focus efforts on collecting transplantable optical grade corneas and avoid wastage.
3. **First priority** (Top priority) of cornea is for emergency graft with good potential and bilateral blindness because of the seriousness of the corneal condition and extent of visual disability of the patient respectively. **“Urgent Listed Patient”** will be the way to register a case that requires an emergency surgery; however, this may not necessarily mean that an optical grade tissue must be arranged. Primary donor failure can also be listed in this category.
 - Criteria for urgent listing for cornea transplant
 - Advanced corneal ulcers/infectious keratitis with progressive worsening/relentless progression/impending perforation/perforation
 - Priority list should be reviewed every 3 months by the State Organ and Tissue Transplant Organization (SOTTO) Cornea Transplant Monitoring Committee/Regulatory Authority
 - If there is a priority patient listed in the CITY WAITING LIST, then the first available transplantable optical grade cornea should go to the priority patient. If there are many patients listed on priority list then the next criteria of selecting the patient will be allocation scoring.
4. **Second priority** is for visually handicapped BCVA \leq 6/60 and \geq 3/60 or endothelial keratoplasty with good prognosis.
5. **Third priority** is for unilateral blindness with good prognosis for visual gain and graft survival
6. **Fourth priority** is for unilateral blindness with poor prognosis for vision and graft survival
 - Allocation in any of the above priority categories will be given to patient having highest score generated out of computerised scoring system. If more than one patient has same score in that category then allocation will be in order of chronological sequence.
7. Cornea from Paediatric donor first will be offered for to paediatric patient. If no paediatric patient eligible, then to adult patient.
8. Cornea retrieved from a government hospital will be allocated as follows
 - Patients listed in Government hospitals list, then Patient listed out of private hospital list
9. Cornea retrieved from a private hospital will be allocated as follows:

- Patients listed in private hospitals list, then Patient listed out of government hospital list
10. In order to minimise wastage, most donated corneas should be allocated within the state, where retrieval has been done.
 11. Allocation will be done first based on city (NCR of Delhi) waiting list. If no recipient eligible in city waiting list then allocation will be done to nearby state in the ROTTO and then to other ROTTO nationally.
 12. In case of hospital which is transplant hospital that does retrieval as well as transplant. One cornea retrieved will be used locally and one should be shared if there is a pressing need in any other centre.
 13. In view of the complexity involved in allocating corneas, the short storage time and the large volumes in comparison with other organs it is best that allocation etc be done by the individual eye banks following the prescribed pattern. SOTTO and NOTTO can play monitoring and regulatory roles respectively as is done by the government administered FDA in USA.

RECIPIENT REGISTRATION, LISTING AND SCORING SYSTEM ON THE WAITING LIST

(to be prepared by corneal transplant surgeon and sent by transplant centre to NOTTO and in house eye bank or CDS)

1. Patient is to be registered by the concerned hospital through online registration form on www.notto.gov.in.
2. Patient should be meeting standard criteria for need for Cornea Transplant and should be Indian citizen till the national waiting list especially of bilaterally blind is cleared
3. International Patient can be registered on humanitarian grounds. Can be considered by the respective SOTTOs, with due permission from competent authority, if there is no local/National patient waiting for the same or if a situation of surplus tissue exists locally at the time so that there is no wastage. They can also be registered and undergo emergency keratoplasty with non-optical grade cornea as these may be in surplus.
4. Patient should be registered Only in One hospital registered under THOTA.
5. Corneal Transplant Centres can submit their waiting list to in house eye bank if available, nearest eye bank and also CDS (Centralized Distribution System).
6. Status of patient must be updated by the hospital monthly for non-urgent and daily for Urgent

ALLOCATION ALGORITHM

Once there is a transplantable optical grade cornea available in eye bank cleared for release, the eye bank should follow the steps outlined below

STEP-1: Check waiting list and follow principle of allocation based on criteria of age/emergency/urgency/government or private hospital

STEP-2: If there is a suitable recipient in local in-house waiting list as emergency/top priority, as per accepted criteria and registered as such, then available cornea will be offered to transplant surgeon/centre responsible for the patient. If there are more than two recipients eligible, preference will be given according to the priority number and ease of access. If two recipients are in similar situation, then allocation will be done in chronological order. If there is no in-house patient, then it should be transferred to central cornea repository for centralized distribution.

STEP-3: If there is no emergency/top priority case, then cornea will go to the recipient in the next priority sequentially i.e. second, third and then fourth.

STEP-4: If there is no locally listed case, then it should be offered to state and then nationally. SOTTO and ROTTO should keep NOTTO updated about priority list in their jurisdiction. Each hospital to maintain their own waiting list which should be notified to the NOTTO.

Reference Notes:

-Cornea retrieved from a government hospital will be allocated as follows

- Government hospitals by rotation.
- If there are no takers in the government hospitals then it will be offered to private hospitals as per the rota,

-Cornea retrieved from a private hospital will be allocated as follows:

- Rota of private hospitals and then
- Rota of government hospitals

-If there is a cornea of borderline grade or status for example age above 80years and endothelial count near 2000 that has been refused by other centre then the centre which agrees to use the cornea will not lose its priority in the next round of allocation.

-Patients (recipients) registered for NCR will need to provide proof of residence within NCR

-Foreign Nationals will be considered only after the cornea is not to be used for any Indian patient in compliance with the law. This will not be applicable for non-optical grade corneas as these are in surplus in India

-If a patient is offered surgery and refuses more than two times then the patient will be pushed back by 2 months.

INTER-STATE ISSUES

1. It is expected that all SOTTOs will broadly follow the same guidelines /protocols for cornea allocation.
2. The appropriate authority of state government in consultation with SOTTO should approve the inter-state transport of corneas for transplantation. As corneas have a limited shelf life a blanket approval should be taken and not required for each and every such situation.
3. All States should agree to share the surplus tissues Nationally to avoid wastage