



Minutes of meeting

Agenda	Meeting on Cornea donation / Retrieval / Distribution and other related issues under chairmanship of DGHS	
Date	14th May 2024	
Time	04:00pm to 05:30pm	
Mode of meeting/ Location	Physical mode / resource centre, Room no 445-A, Nirman Bhawan, New Delhi	
Meeting chaired by	Dr. Atul Goel, DGHS	
Minutes Vetted by	Dr. Anil Kumar, Director NOTTO	
List of participants	<p>Ms. Vandana Jain (JS) Dr. Naresh Panchal (Addl. DDG) Dte.GHS Dr. Rajneesh Sahai (Ex Director NOTTO) Prof. (Dr) Radhika Tandon (National eye bank AIIMS, New Delhi) Dr. Sarita Beri (Director Prof. Ophthalmology) LHMC. Prof. (Dr) Namrata Sharma Eye Bank . Association of India, (EBAI) AIIMS, New Delhi) Prof. (Dr) Rajshekhar (Asst. commissioner, NPCBVI (Consultant prof. SJH) Dr. Shikha Jain (CMO, NFSG) RMLH. Dr. Gaurav Kumar (M.O), RMLH Dr. Yogita Gupta (Asst. Prof. Ophthalmology) LHMC & SSKH Ms. Rakhi Nathawat, Senior Manager, EBAI SCEH Dr. Manisha Acharya, Director Dr. Shroff's Charity Eye Hospital (SCEH) network Dr. Parul Jain (Associate Prof. Guru Nanak Eye Centre) Dr. Supriya Dhar (Associate Prof. AHRR) Dr. Nishita Aggarwal (Med. Director EBCRC, Mumbai) Dr. Jaswant B Mehta (Managing Trustee) EBCRC, Mumbai Dr. C Aparna (DGHS) Ms. Ankita Gupta (SO, MG) Dte.GHS Dr. Rahul Pandey (consultant, NPCBVI)</p>	<p>NOTTO Dr. Anil Kumar, Director Dr. Shiny Suman Pradhan (CMO) Dr. Awadhesh Kumar Yadav (CMO) Dr. Rajesh (consultant) Dr. Braj Bhushan Ojha (consultant) Dr. Archana Kumari (consultant) Mr. G Shri Ram (DEO)</p>

Minutes are summarized as points given below: -

After welcome and introduction, it was informed by Director NOTTO that following three (3) representations have been received by NOTTO regarding Cornea related issues.

1. One from **Ms. Uma Jhavar**, Executive Director, MK International Eye bank, where in suggestions have been made for increasing eye retrieval centres at block & District level and the need for eye/cornea retrieval trained manpower.
2. **Sh. Praveen Chandra**, wherein he has represented that due to unavailability of death certificate, his friend's family could not full fill his last wish for eye donation.
3. **Sh. Jaswant B. Mehta**, Chairman – Advisory Board & Managing Trustee of the Eye Bank Research and Coordination Centre, Mumbai wherein he has requested for amendment in The Transplantation of Human Organs & Tissue Act (THOTA), 1994 for purpose of de-linking of Cornea from other organs

In view of above representations, the discussion points of meeting were proposed as follows:

1. Situation analysis in respect of training needs in Cornea donation, retrieval, Cornea Registry, Banking and Distribution
2. To develop curriculum and module for Cornea/ Eye Retrieval / Excision
3. Continuation of cornea donation and transplantation under THOTA 1994
4. Discussion about amendment of the rules of Eye Banking and Cornea Transplantation under THOTA in reference to suggestions received from Sh. Jaswant B. Mehta, Chairman-Advisory Board and Managing Trustee of the Eye bank Research and Coordination Centre, Mumbai
5. Suggestions for opt-out system of Cornea donation in case of institutional deaths at tertiary care centres.
6. Discussion regarding scarcity of cornea storage medium and its solution.

DGHS invited **Mr. Jaswant Mehta** who was physically present in the meeting to elaborate on his points of representation. **Mr. Jaswant Mehta** stated that different rules for cornea donation be framed as cornea can be retrieved in normal death cases and also at home. He emphasized on following points:

1. The requirement for registration of Corneal Transplant Centre under THOTA, 1994 should be done away with, as unlike other organ like Liver, Kidney, Heart etc. a Corneal transplant is much simpler procedure. It is similar to other eye surgeries such as Retinal detachment or surgery for glaucoma etc.
2. According to the Rule 28 (8), "Corneas or eyes not found suitable for transplantation and their alternate use shall be certified by the Committee of two Ophthalmologist" The said rules need to be amended as the corneas are screened & evaluated by the trained technicians as permitted under rule and Medical Director attached to the Eye Bank is competent to certify the suitability. There is no need for separate committee (**Rule no 28(8)** In THOTA 1994) to grant permission for the discarded cornea for the use of research purpose.

3. The provision for consent for eye donation needs to be included in the Medical Cause of Death Certificate and should be mandatory in the rules under THOTA. Similar consent should be included in the postmortem consent forms also. In places where there is eye bank within reachable distance it should be mandatory to inform the nearest eye bank for making necessary arrangements for collection of eye balls/corneas. It will minimize the need for hiring counsellors and the cost of eye banking. He also submitted a copy of representation given by Dr. Keshwani to include the skin with cornea where ever possible while amending the rule or the act, as parameters for skin retrieval after the death are the same as those of cornea.

The opinion/comments/inputs of the participants are given under:

DGHS agreed with Mr. Jaswant Mehta's suggestion that requirement for registration for cornea transplant centers under THOTA 1994 may be reviewed. **DGHS** suggested that self-declaration could be enough and presumed consent with optout system may be worked out for boosting cornea donation. **DGHS** asked that a checklist may be provided to cornea transplantation centre for giving the undertaking or self-declaration. **DGHS** discussed about the problems for cornea retrievals, which came to his notice even from big hospitals in Delhi NCR, when residents of Dept of Ophthalmology refused to collect cornea on the pretext that they are not trained. He also discussed regarding the scarcity of preservative fluid required for cornea storage.

Dr. Radhika Tandon stated that requirement for cornea donation is huge and India is able to meet only around 50 % of its requirement. She also supported that registration for cornea transplant may be simplified. As in practice, the current process can sometimes become an unnecessary legal hurdle for corneal transplantation surgeries especially when renewal of registration is delayed due to some administrative problems then the corneal transplant activities have to stop. This process should be reviewed and simplified especially if it is a case of renewal of registration for an approved cornea transplant centre. She also agreed for presumed consent and optout system for cornea donation. She said that trained technician cannot certify death so they always send a doctor with technician for home retrieval in their organization. But in hospital, as doctor is available, the trained technician is allowed to retrieve cornea.

Dr. Namrata's opinion was to continue with the registration for the transplant centers for corneas, as all the general Ophthalmologist are not trained enough for cornea retrieval and transplantation. She suggested about the need for the technical training for medical professionals regarding cornea transplantation and retrieval.

Dr. Rajshekhar stated that there are estimated 726 registered eye banks in the country, but only 200 are operational. He also mentioned that most of the registrations sought by the hospitals are for PG seats only and during inspections many times deficiencies have been found regarding availability of required good quality equipment, infrastructure and manpower for cornea transplantation and eye banking. He said that they have checklist for registration which is primarily the Form 15 of the THOTA rules 2014. He disagreed for the inclusion of technician in the committee for cornea evaluation/assessment as the technician is not trained

to do so & may also not be from medical field. He also stated that Eye bank standards of India published by NPCB&VI in the year 2020, has included all guidelines for training in eye retrieval /excision of cornea and no further guidelines are required.

Dr. Sarita Beri opined that the registration for cornea transplantation may be taken off. She gave an example of how sclera is sometimes used for glaucoma or other surgeries and when there were some patients to be operated with scleral grafts at LHMC, they were given conflicting opinions on whether this requires registration as a transplant centre which led to a lot of confusion and hampered patient care services. Hence, she suggested that this requirement should be removed.

She also highlighted the need for "omission of waiting for postmortem before eye retrieval as cornea collection does not disfigure the face of the deceased or change post-mortem findings in any way". Delay in retrieval of corneas while waiting for postmortem in MLC deaths leads to time lapse, which becomes a contra-indication for eye retrieval.

Dr. Yogita Gupta suggested that Corneas may be allowed to be retrieved before postmortem (PM) & NOC for cornea retrieval to be given before PM, in medicolegal cases. Section -6, THOTA may be modified accordingly to delink cornea from other human organs as cornea, unlike other organs, is retrievable upto 6 hours after death.

DGHS asked that budget for perfusion/preservative fluid/medium may be provided by NOTTO for Govt. as well as private eye banks, but emphasized that private hospitals/eye banks should do free retrieval of corneas against this. **DGHS** also asked NOTTO to collect information and data regarding activities in last 3yrs. by registered eye banks.

Dr. Manisha Acharya gave information regarding the challenges faced by transplant centers especially delay in grant of registration and renewal.

Director NOTTO gave reference of **form 8 in THOTA rules 2014**, which is applicable for giving consent for cornea retrieval also. Regarding inclusion of the consent column for eye donation in the Medical Cause of Death Certificate, it is not in the domain of THOTA 1994 and can be considered by concerned department (Registrar General of India) or by the concerned Ministry (Ministry of Home Affairs).

He stated that death certificate is not required for cremation in natural death (or death at home). He also stated that cornea donation can be considered in Medicolegal cases, as cornea is avascular tissue and most of the time not required for determination of cause of Death. Further he mentioned that facility for registration of patient for seeking cornea for transplant, registration of deceased donor is available on the NOTTO main website www.notto.mohfw.gov.in . Facility for registration of those who wish to pledge for cornea donation after death is available on the dedicated portal www.notto.abdm.gov.in .NOTTO Cornea allocation policies is available on the main NOTTO website under the tab Guidelines. Transport of corneas may be allowed as per NOTTO allocation policies, once the registry is put

in place. The transplant coordinator provided under NOTP programme is also required to encourage and counsel families of potential donors for cornea donations besides donation of other organs and tissues.

Mr. Jaswant Mehta informed that however, in Mumbai, death certificate is mandatory for cremation.

DGHS asked Sh. Jaswant Mehta that how long it will take to issue death certificate for home death in Mumbai, to which he could not give a definite reply. **DGHS** agreed that in MLC cases, corneas may be allowed to be retrieved before postmortem (PM) & NOC for cornea retrieval to be given before PM. **DGHS** inquired about wastage percentage of corneas, which was informed to be around 50%. **DGHS** asked the experts for rethinking on registration for transplant centers, but he stated that there is no need of registration of retrieval centres for corneas. He agreed that evaluation/assessment of corneas cannot be done by technician only.

It was informed by Dr. Manisha from Shroff eye bank that they have a structured modular training for eye retrieval and maintain a logbook of activities to be performed before the certificate is granted. She agreed to share the same. **DGHS** stated that the training certificate should have all the relevant details.

Dr. Rajneesh Sahai emphasized on need for adequate number of eye donation counsellors in cornea donation Programme, which are absolutely essential.

After discussions and deliberations, following action points were decided:

1. As a policy, Presumed consent for retrieval of Cornea in all cases of hospital deaths of Indian citizens unless the person had opted out during his lifetime, should be implemented. It means that cornea can be retrieved from all Indian citizens who die in hospitals without any requirement of consent of family, however, those who do not want cornea to be retrieved can register their dissent while they are alive. This policy will require amendment in the THOTA 1994. **(Action: NOTTO & MoHFW)**
2. It was agreed in principle that registration of a cornea transplant center may not be made mandatory. It may be granted based on self-declaration by the head of the hospital in a standard check list format as per Form 15. However, this will require amendment in the THOTA 1994. **(Action: NOTTO & MoHFW)**

Till then current process of registration will continue, however the State Appropriate authorities will be requested to expedite the process of grant of registration or renewal and hospitals will also be required to apply for renewal well within the permissible timeline defined under the Act and Rules. NOTTO will write a letter to all State Appropriate authorities in this regard. **(Action: NOTTO)**

3. NOTTO will also write to States/UTs for mandatory registration of licensed Cornea transplant centres and Eye Banks with NOTTO national registry and States should collect

data on cornea donation and transplantation from all registered centres and furnish the same to NOTTO on monthly basis either on their own or direct hospitals to do so. The hospitals should be encouraged to enter the details digitally in the NOTTO registry.

(Action: NOTTO)

4. Registration/license for cornea retrieval is not required. However, the Eye Banks shall provide the list of their associated Cornea donation/retrieval centres to State Appropriate Authority. Further, the Eye banks while registering with NOTTO, shall also provide the list of their associated/feeder cornea donation or retrieval centres. Further Eye banks will be required to take the responsibility of maintenance of required standards as per THOTA, 1994 by their affiliated retrieval centres. A letter in this regard may be issued to States/UTs for compliance by the eye banks. **(Action: NOTTO)**
5. A letter would be sent from DGHS to Niti Aayog to facilitate commercial production of cornea preservation medium at a lower cost with make in India provision. **(Action: NOTTO)**
6. A provision under National Organ Transplant Program (NOTP) shall be made for supply of cornea preservation medium for Government Eye Banks as well as Private Eye Banks. The same can be provided by NOTTO to all eye banks. The budget provision shall be made under NOTP. **(Action: NOTTO & NOTP division)**
7. Private Eye Hospitals & Private Eye Banks shall be asked to do cornea retrieval whenever needed and they will provide the service free of cost as part of their CSR activity. The States would be requested to issue necessary directions in this regard. **(Action: NOTTO & MoHFW)**
8. NOTTO will issue a circular to all medical colleges and hospitals that all PG trainees, resident doctors, medical officers working in eye departments must be given compulsory training in cornea/eye retrieval. Further, they will be involved in collection of corneas from the field. NPCB&VI will also coordinate for implementing the same. **(Action: NOTTO, NPCB&VI)**
9. Training of technicians in cornea/eye retrieval shall be instituted by all States/UTs as per the Guidelines contained in the Eye Bank Standards of India 2020, through the identified training centers/large registered eye banks, whether in Government or Private. The work will be coordinated by NPCB&VI division of Dte.GHS and Ministry. All major Eye institutions and Eye banks may be involved for starting of training course for cornea retrieval in training of trainers' mode initially. **(Action: NPCB&VI)**
10. NPCB&VI will draft a Proposal to provide trained technician and eye donation counsellors for augmenting eye donation, to all Government eye institutions from NPCB&VI budget. **(Action: NPCB&VI)**

11. NOTTO will write to all States/UTs for collection of data from all registered eye transplant centers and eye banks and to furnish information regarding their activities in last 3yrs including information on corneas that were not transplanted/utilized (state-wise). The State Appropriate authority will examine the data on eye/cornea collection annually and in case of less performance (less than 50 eye/100 cornea collections per year), the State Appropriate authority shall issue a warning notice to the eye bank to augment their eye donation activities otherwise their renewal may not be granted. **(Action: NOTTO)**

12. **Dr. Manisha from Dr. Shroff Eye Centre will share training module and logbook which they already have and use for training staff in eye retrieval. (Action: Dr. Manisha)**

The Meeting ended with vote of thanks to & from the chair.
