## EYE BANKING FOR DEVELOPING COUNTRIES IN THE NEW MILLENNIUM

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## Introduction

Corneal Blindness in the developing world has traditionally been attributed to trachoma, xerophthalmia, neonatal ophthalmia, measles and leprosy. In India 1.52% are blind from corneal opacities (National Survey) 86-89<sup>1</sup>. In the Nepal blindness survey, corneal trauma and ulceration were found to be the second leading cause of unilateral vision loss after cataract accounting for 7.9% of all blind eyes<sup>2</sup>. In Malawi<sup>3</sup>, Tanzania<sup>4</sup> and Bangaladesh<sup>5</sup>, corneal scarring was found to be responsible for 39-55% of all cases of unilateral blindness. Survey in blind children in Africa have shown that approximately 70% if all blind disability in this group is caused by corneal opacification<sup>6</sup>.

The requirement of corneas in India is about one lakh annually. The number of eyes being procured annually is only about 17,000 of which only about 50 to 60% are utilized. This clearly indicates a gap between the supply and demand. There are about 200 eye banks in the country of which only about 30% are functional. Most of these are functioning more like collection centers rather than eye banks. There are very few Eye Banks, which maintain required quality. There is a need for organizations, and individuals to come forward and work towards promotion of eye donations, and procurement of eyes, in a country where home deaths are common, so as to try and address this need in the next millenium.

## Methodology

As soon as a home death occurs, a family member calls the eye bank and informs of the demise and their willingness to donate. The contact is via telephone and details such as donor, name complete address, nearest landmark and telephone number is given to enable the eye bank team to identify the donor address easily. At this time of contact the following instructions are given:

- Raise the head of the donor slightly by placing a pillow.
- Close the eyelids
- Switch off fans.
- Keep Air conditioner on if it is there.

A few minutes later the eye bank calls up the given telephone number just to verify the incoming call. On reaching the house, the eye bank team members first introduce themselves and pay homage to the departed. Then they speak to the senior family members, and obtain the consent of the next of kin with of two witnesses. During this conversation the name and age of donor, cause of death, and information on whether the donor was hospitalized is noted down. If hospitalized, whether the donor was on a ventilator, whether blood transfusion was

given and had any neurological problem. All this information is documented prior to enucleation.

#### The enucleating procedure

Since most of the deaths in India are home deaths, there is need for strict asepsis care, caution and sterility being maintained throughout the procedure. First make a cursory examination of the cornea with a torch. At this time also quickly observe for evidence of drug abuse. Clean the area around the eyes, eyelids, nasal area and forehead several times. This must be done in a centrifugal manner. The cleaning should be done with alcohol pads first and then with betadine. Now drape the donor and prepare a sterile field so as to place the instruments and the eye jars. Apply antibiotic drops (approximately 25 to 30 drops).

Open the eyelids using a sterile applicator and a speculum is inserted. Using a small clawed forceps and tenotomy scissors, lift and cut the conjunctiva at the limbus 360°. The four-rectus muscles are successfully looped with a muscle hook except for the lateral rectus. Cut the muscles. Before cutting the lateral rectus, clamp it close to the eye, then cut the muscle distant to the clamp. The two oblique muscles and the optic nerve now remain. When lifting up the clamped lateral rectus muscle, insert the curved enucleation scissors between the conjunctiva and the globe. Locate the optic nerve by feel and cut leaving at least ¼ inch of the nerve attached to the globe. Now place the globe in the eye jar and note on the jar which jar contains which eye. Ensure that the chamber is moist. Instill about 25 to 30 drops of antibiotic solution (Neosporin or Genticyn) over the cornea before screwing the lid. Now label the eye jar and reconstruct the face socket.

## Drawing blood

This has become mandatory for all eye banks. With the prevalence of HIV and HBsAg increase, no one can afford to take risks. Blood should never be drawn downstream from an IV site to avoid hemodilution. Always angle the needle in under the skin, apply a slight back pressure on it by withdrawing the plunger about half an inch. This creates suction to draw in blood when the vessel is found, indicated by the sudden flow of blood into the syringe. When this occurs, withdraw the syringe just enough to fill it completely. Usually gentle probing with the needle is necessary to locate the vessel. Once blood is drawn, insert the syringe into the vacutainer tube. Hold the plunger firmly while piercing the vacutainer. Ensure that the blood is made to drip along the sides of the vacutainer tube slowly during the transfer process from the syringe. Ideally a 10- cc syringe with an 18-gauge needle should do. 5 to 10 cc of blood should be drawn. Let the vacutainer containing blood slant at an angle of about 30° for about 5 minutes to separate the serum thus preventing lysis of blood before being packed. During this process the technician should wear a gown, cap, mask and gloves for their safety.

Blood can be drawn from the Subclavien vein, Jugular Vein, Femoral Vein, or from the heart. Drawing from the femoral vein requires the least amount of training but yields the least amount of blood. Drawing from the jugular vein is most difficult and needs tremendous skill and yields maximum blood.

# Packing for transportation

- The ideal container should be a Styrofoam container or any igloo container which maintains the temperature between 2° and 8°C
- Never use dry ice for packing. Place water in a small plastic container and freeze. Before
  packing remove the container with ice and keep at room temperature until the moisture
  begins to form on the top of the ice. At this point, close the lid and place the ice pack in a
  polythene wrapper and seal. In this manner the temperature of the ice will be maintained
  for longer duration.
- Place the eye jars and the vacutainer containing blood, between these containers of ice in a moist sponge.
- If Styrofoam containers are used just wet the Styrofoam box on the outside to maintain the temperature.
- Ensure that the consent form, evaluation and donor history is sent along with the package.

All these precautions are necessary to ensure that the eyes reach their destination safely.

# Quality control

This is the key to proper utilization of any cornea. Not only during the enucleation process but even more after the eyes are brought to the eye bank for processing. The entire processing should be performed under sterile conditions. The processing that follows once the eyes are received at the eye bank is as follows:

- Tissue evaluation
- Corneal excision and preservation
- Serology
- Documentation
- Distribution
- Preservative mediums

## **Tissue evaluation**

As soon as the eyes are received at the eye bank, the whole globe is evaluated and graded. A careful examination of the cornea under a slit lamp is necessary. Examine the epithelium for haze, exposure, sloughing or any other epithelial defects. Then see the stroma if it is clear or cloudy, whether arcus senilis is there and opacities if any. Check for folds in the descemets membrane and an observational evaluation of the endothelium. It after this examination the cornea is found to be good then it is excised.

# **Corneal excision**

This procedure should be performed in a sterile environment under aseptic conditions as far as possible. If the environment where the donor is offers these conditions you may do a corneal excision and transfer the cornea to the preservative medium immediately. As most deaths are home deaths and environmental conditions may not be suitable for corneal excisions, it would be safer to enucleate the whole globe and perform the corneal excision in the eye bank, under the Laminar Air Flow (LAF) in sterile conditions, thus improving the quality of the tissue. By using the glove and gown technique we improve the asepsis of the entire procedure thus avoiding contamination.

# Serology

This is now mandatory for eye banks, due to the increase in the prevalence of diseases such as HIV and HBsAG etc. At least 5 cc of blood must be available for performing serology. The sample should preferably collected in plain silicone coated vacutainer which is inexpensive. There are many test kits that are available to use. Sterility of the procedure should be maintained. Adhere to all the safety measures as indicated. Avoid contamination or direct contact with the serum. Work under a Laminar Air Flow. Decontamination should be done as per the guidelines set. Ensure that the work surfaces are cleaned with 70% alcohol prior to and after use.

## **Preservative mediums**

The most commonly used preservative mediums are MK and Optisol. MK medium is easily available in India as it is produced by the support of Rotary at Hyderabad and supplied to only recognized eye banks. Corneas can be preserved in this medium from 72 hours to 96 hours. The other medium is Optisol. This has to be imported and costs approximately US\$42/- per vial. Corneas can be stored in this medium for 10 to 14 days. Check to see that the color of the medium has not changed as that would indicate a change in the pH value due to contamination.

## Documentation

This is absolutely essential for all eye banks. As we are dealing with tissue that is being recovered from cadavers and being grafted to human recipients, this document is a testimony for any medico legal purpose in the future. Also this is a document for all the processing and procedures that is preformed to maintain the standards and hence is an invaluable document.

## Distribution

Corneal tissues may be distributed to ophthalmic institutions, corneal surgeons and other eye banks. The emphasis here is in the packing and transportation. Ensure that the corneas are maintained between 2 and 8° during the transportation process. Also see that the various documents such as tissue evaluation, serology, and donor information reports are enclosed. Use of Styrofoam containers are advisable, as these will maintain the temperatures as well as withstand the journey. However even gas sterilized empty film roll container can also be used as the globe fits snugly into the container<sup>7-8</sup>.

### Quality

From the quality control aspects for eye banking, a regular regimen for cleaning of the eye bank should be maintained. Disinfection of instruments must be performed very meticulously and as per the disinfecting procedure. The sterility of the eye bank will be maintained, if the cleaning procedures are maintained as per the procedure. It is important to maintain this in similar fashion to an OR, except that you should UV radiate and not fumigate.

## **Regulatory body**

The regulatory body (Non Governmental) in our country is the Eye Bank Association of India (EBAI) which Headquarters at Hyderabad and has its zonal offices. The other regulatory body is the International Federation of Eye Banks (IFEB) which is for International Eye Bank and is situated in the US. International eye banks are affiliated to both, regional and international body.

### Discussion

Good Eye Banking practices depends on proper quality control. This can be further bifurcated in clinical and non-clinical practices. In the clinical practices details such as sterile procedures, correct evaluation, good documentation procedures, proper disaffection methods being used and proper packing are important. On the non-clinical side, courteous telephonic conversation, documentation of correct information, prompt and immediate action, and sensitivity to the situation are all very important. Corneal retrievals could be either directly from the donor home or from a hospital. In our country where home deaths are common, it is important that we try and maintain asepsis of the procedure as far as possible to maintain quality, at the same time is sensitized to the situation of the donor family.

From our data for 1998 we found that the nearly 62% of the eyes that we received were from donors in the age group of 60 to 80 years, most of the causes of death being respiratory failure. With the prevalence of HIV and HBsAG on the increase, it has become mandatory for all eye banks to perform serology tests for the above as well as syphilis. Despite the documentation of HIV in tears<sup>9</sup> and donor corneal tissue <sup>10-14</sup>, the potential for transmission via corneal transplant is very low. There have been no reports so far of sero conversion after

corneal transplant. Some patients who received corneas from HIV infected donors, showed no evidence of sero conversion <sup>15-16</sup>. Nevertheless the potential of transmission is too great to take undue risks.

Transmission HBV through corneal transplant has been documented in the case of two different donors<sup>17</sup>. Recipients from one cornea from each donor developed clinical and serological evidence of HBV infection, 14 weeks after keratoplasty performed, without prior serological testing. The other recipient of the other donor, developed clinical conditions but tested positive, two years after penetrating keratoplasty. However there have been no reported cases of syphilis having been transmitted through corneal transplant.

Recent studies indicate that there is a poor correlation between reactive syphilis and HIV testing in potential cornea donors<sup>18</sup>. However every test has a cost associated not only in terms of money but also in false positives and tissue wastage. Implementation or abandoning tests should be based on strong scientific data. In developing countries attention must be paid to the cost factor and hence it is necessary to use the most suitable and appropriate equipments.

#### Conclusion

With the demand for corneas on the increase and the limited supply, it is imperative that the corneas received must be utilized to the maximum. Currently the utility rate ranges between 25% and 60%. In developing countries where the demand is so great, it is imperative that quality is maintained at all the various stages of the process to ensure a higher utility and lower wastage. In teaching Institutions there is no wastage. The sclera are also preserved in absolute alcohol and utilized for orbit surgeries. The focus in eye banking in the developing countries in the next millenium will have to be towards increase in corneal procurement, high quality and better utilization of all the donor corneas received and lower costs.

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