

EYE BANKING

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- Eye banks are *non-profit* organizations with a mission to *procure* and *provide* donated human eye tissue for *sight restoring* transplantation procedures as well as providing vital tissue for *research* and *education*.

- Eye bank could serve 4 – 8 eye donation centers covering an area of 8 – 15 lakhs.

- Eye donation center procure at least 20 pairs of eyes annually from an operative area of 2 –3 lakhs.

OBJECTIVES OF AN EYE BANK:

- ü Collection of donor eyes.

- ü Process & storage of donor cornea.

- ü Distribution & storage of donor cornea.

- ü Distribution & utilization of highest quality of donor tissue for transplantation.

- ü Provide for soliciting eye donation from potential donors.

- ü Provide & process eye tissue for teaching /research, as needed.

- ü To promote public education relation system.

- ü To promote hospital cornea retrieval programme to improve collection of donor eyes from hospital deaths.

Facilities (Organization and Infrastructure)

For an efficient eye banking system, a three tier organizational structure has been recommended. At the top of the pyramid is the “Eye Bank Training Center” followed by “Eye Banks” and at the base of the pyramid is the “Eye Donation Center”.

Procedures manual:

Each eye bank shall maintain its own procedure manual (SOP) that details all aspects of its specific retrieval, processing, testing, storage, distribution and quality assurance practices. Each procedure must be initially approved signed and dated by the Medical director or Officer-in-charge of the eye bank. An annual review of each eye bank’s procedures manual with signing and dating by the Medical director or Officer-in-charge is required. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use.

The following facilities and infrastructure is required

Physical space:

A minimum area of 600 Sq.Ft is required which accommodates a serology lab, tissue processing lab and evaluation, storage & shipping lab.

Infrastructure:

Instrument Cleaning Lab:

1. Sink – For washing instruments
2. Autoclave for sterilizing
3. Counter top & storage space for storing instruments & supplies

Serology Lab

1. Sink for washing
2. Refrigerator – For storing blood samples & kits
3. Counter tops, cabinets & drawers for workspace and storing supplies
4. Centrifuge & Serum testing equipment like ELISA Reader, Rapid test etc.

Equipment	EBTC	EYE BANK	EYE DONATION CENTER
Transportation Facility	24hour 365days	24hour 365 days	Should have access
Furniture	required	required	preferable
Computer with email facility	required	required	preferable
Two exclusive lines (one with 1919 or public service number allotted and another for outgoing calls to be allotted)	required	required	Universal public number allotted
Audio visual equipment for publicity	required	required	preferable

Tissue Processing Lab

1. Sterile counter / table top for processing (Laminar Flow Hood / Bio-Hazard Cabinet)
2. Counter tops, drawers and cabinets for Storage

Evaluation, Storage & Shipping Lab

1. Slit Lamp and Specular Microscope for Tissue Evaluation.
2. Counter Tops and Cabinets for Storage of Supplies Packing and Shipping.
3. Refrigerator for Storing Donor tissue Equipment EBTC EYE BANK EYE DONATION CENTER

Transportation Facility 24hour365days
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Eye Bank Maintenance

- The room including walls, floor and sink must be kept clean at all the times. Appropriate documentation of regular laboratory cleaning

schedules must be maintained and kept on file for a minimum of three years..

- Each eye bank laboratory must have an adequate, stable electrical source and sufficient number of grounded electrical outlets for operating laboratory equipment.

Equipment maintenance and cleaning:
 Refrigerator:

- Each eye bank laboratory shall have a refrigerator with a device, internal or external for recording temperature variations. Temperature variations must be recorded twice daily and should remain within the range of 2° – 6° C.

• The refrigerator should be maintained exclusively for use by the eye bank. It must contain clearly defined and labeled areas for all tissues stored e.g. surgical tissue, awaiting distribution, quarantined tissue, tissue for research etc.

- The refrigerator should be calibrated once a year.

Laminar Airflow Hood / Cabinet:

- The cleaning schedule should be maintained.
- Particle counts should be performed once a year.

- Appropriate maintenance and accreditation records must be maintained for each piece of equipment.

- The eye bank must include in its procedure manual, the monitoring, inspection and cleaning procedures and schedules, for laboratory equipment. These must be kept on file for a minimum of three years.

- In the event of power failure there must be provision for immediate notification and action to be taken, which may include an emergency power supply to maintain essential refrigeration.

- Adequate instruments must be available to provide for sterile removal of whole eye and corneas.

- Instruments must be inspected frequently enough to assure that they function properly.

All sterilized instruments, supplies and reagents, such as corneal preservation medium, must contain expiry dates that are current at all times.

Infection control and safety:

All eye bank personnel must operate under the universal precautions for health care workers. These written procedures must be included in the eye bank’s procedure manual. All technical personnel should receive Hepatitis B vaccination and any other recommended vaccination that may be announced from time to time.

Waste disposal:

Human tissue and waste items shall be disposed off in such a manner as to minimize any hazard to eye bank personnel and the environment and comply with applicable regulations. Dignified and proper disposal procedures shall be used to obviate recognizable human remains.

COLLECTION:

Person can pledges before death to donate his eyes. No living person can donate

his eyes, because the law does not permit it. Similarly eye tissue cannot be sold or purchased. After getting information of death & proper written consent from the next of kin, eye bank personnel can collect the eyes.

The eye ball should be collected within 4-6 hours of death. Age of donor, time of death, cause of death Is important before enucleation. Most eye bank accept eyes from donors between 6months to 80 years.

Two method of procuring donor tissue for the eye bank:

- Voluntary donation
- Hospital cornea retrieval programme (HCRP)

The eye bank association of India has come up with a novel cornea collection strategy called HCRP. This programme was initiated by Ramayamma International Eye Bank at L V P Eye institute Hyderabad in 1990. Eye donation counsellor is appointed for this purpose.

ADVANTAGES of HCRP:

- Access to younger & healthier tissue.
- Availability of donor medical history.
- Higher utilization & success rate.
- More scope of training & future research.
- Cost effective.

Conditions with potential risk of transmission of local or systemic communicable from donor to recipient

- Death of unknown cause
- Death with neurologic disease of unestablished diagnosis
- Subacute sclerosing panencephalitis
- Progressive multifocal leukoencephalopathy
- Active meningitis or encephalitis
- Encephalopathy of unknown origin or progressive encephalopathy

- Active septicaemia (bacteremia, fungemia, viremia, parasitemia)
- Active viral hepatitis
- Creutzfeldt-Jakob disease
- Congenital rubella
- Reye's Syndrome
- Active miliary tuberculosis or tubercular meningitis
- Patients on ventilator for > 72 hrs
- Hepatitis B surface antigen positive donors
- HTLV-I or HTLV-II infection
- Hepatitis C Seropositive donors
- HIV seropositive donors
- Parkinsonism

Conditions with potential risk of transmission of non-communicable disease from donor to recipient.

- Death due to cyanide poisoning
- Intrinsic eye disease
- Retinoblastoma
- Malignant tumours of the anterior ocular segment or known adenocarcinoma in the eye of primary
 - metastatic origin
 - Leukemias
 - Active disseminated lymphomas

(III) Conditions that will affect graft outcome.

- Congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use e.g., a central donor corneal scar for an intended penetrating keratoplasty for keratoconus and keratoglobus. Corneas which have undergone refractive surgical procedures etc.
- Patients on ventilator for >72 hrs.

Behavioural / History, Laboratory and Medical Exclusion Criteria.

- Men who have had sex with other men in the preceding 5 years (homosexual behaviour)
- Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years. (IV drug abusers)
- Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrate.
- Men and women who have engaged in sex for money or drugs in the preceding 5 years (commercial sex workers)
- Persons who have had sex in the preceding 12 months with any person described in item a-d above or with a person known or suspected to have HIV infection.
- Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, or mucous membrane.

In situ and laboratory removal of the corneoscleral rim:

Individuals specifically trained for in situ retrieval and/or laboratory removal of the corneal scleral segment shall perform removal of the corneal scleral rim using sterile technique. If the procedure is done in a laboratory the removal must be performed in a laminar flow hood, cabinet or in an operation Theatre .

Use of short or intermediate term preservation medium:

Eye Bank shall use approved corneal storage medium (such as MK, Optisol GS, EUSOL, etc) from a reliable source. The medium shall be used and stored according to the manufacturer's recommendations for temperature, date and other factors. The manufactured medium purchased and shipped to the eye bank shall be inspected for damage upon arrival and the lot number of medium used for each cornea shall be recorded on the

tissue tracking and recall.

Long term preservation

Some eye banks employ long-term preservation of corneal tissue, such as **glycerine preservation** or **organ culturing**. An eye bank that use long-term preservation shall carefully document the procedure in their procedure manual, and adhere to rigid aseptic technique.

Whole globe preservation

Eye Banks that store whole eye shall employ aseptic practice. The selected preservation method must be documented in the eye bank’s own procedures manual.

Sclera preservation

Eye banks shall preserve scleral tissue aseptically. The selected preservation method must be documented in the eye bank’s own procedure manual

Tissue Evaluation Standards:

The corneal scleral segment should be examined grossly for epithelial defect, foreign body, contamination, sclera colour.

■ Cornea examined under slit lamp for epithelial & stromal pathology.

üDetermination of endothelial cell density via specular microscopy. DONOR BLOOD SCREENING:

■For HIV,Hep-B ,Syphilis, Hep-C

Eye Banking System

■For efficient functioning of eye banking system a three tier structure has been developed. At the top are Eye Bank Training Centers numbering five, one each for the five zones in the country, followed by 45 eye banks. These 50 eye banks and eye bank training centers are networked with 2000 eye donation centers.

Eye Donation Center (EDC)

Eye Donation Center is affiliated to a registered eye bank, which should provide

- (1) public and professional awareness

about eye donation

- (2) co-ordinate with donor families and hospitals to motivate eye donation

- (3) to harvest corneal tissue and collect blood for serology

- (4) to ensure safe transportation of tissue to the parent eye bank.

Eye Bank (EB) is an institution that should

· Provide a round-the-clock public response system over the telephone and conduct public awareness programmes on eye donation.

· Co-ordinate with donor families and hospitals to motivate eye donation Hospital Cornea Retrieval Pgramme– (HCRP)

· To harvest corneal tissue

· To process, preserve and evaluate the collected tissue

· To distribute tissue in an equitable manner for Keratoplasty

· To ensure safe transportation of tissue.

Eye Bank Training Centre (EBTC):

All of the eye bank functions plus training for all levels of personnel in eye banking and research.

Awareness:

The main activity of an eye donation center, eye bank or eye bank training center is to create awareness about eye donation and also educate public about the need for eye donation.

Awareness campaigns can be **General awareness campaigns** and **Focused awareness campaign**.

Responsibilities of various eye banking personnel

Board of Directors:

All EBs and EBTCs need to have a board of directors or equivalent committee composed of medical professionals and other professionals who could contribute to the smooth functioning of the organization.

Medical Director / Eye Bank Incharge:

· The Medical Director (MD) must be an Ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research or teaching in cornea and/ or external disease or has an experience in corneal transplantation. If the eye bank does not have such a person it should have a consulting relationship with an ophthalmologist who satisfies the above criteria.

· All policies and procedures of each eye bank shall be under the supervision of the MD.

· The MD shall be providing all staff members with adequate information to perform their duties safely and completely.

MANPOWER EBTC, EB ,EDC:

· Board of Directors or equivalent Committee

· Medical Director (MD) or equivalent

· Executive Director (ED) or equivalent such

· Officer-in-charge

· Eye Bank Manager (EBM) or equivalent

· Eye Bank Technicians (EBT)

· Eye Donations Counselors (EDC)

· Administrative Secretary cum telephone operator

· Driver

· Panel of Registered Medical Practitioners to enucleate round the clock.

Executive Director or Designated Equivalent:

Will be responsible for managing the entire operations of the eye bank. It is the responsibility of the Executive Director to follow the policies of the Board or committee and wherever necessary shall consult the Medical director/Eye Bank incharge or other specialists for discharging the responsibilities.

Eye Bank Manager or Designated:

Eye bank manager will be responsible for

the day to day functioning of the eye bank and ensure compliance with the set standard .

Eye Bank Technicians:

· Shall be responsible for the entire activities of eye banking like retrieval, processing, evaluation, documentation, distribution of tissue and maintenance of the laboratory and instruments and equipment.

· He / She shall be Higher Secondary qualified with Science or Higher Secondary education with experience in a diagnostic or similar lab or experience in operation theatre procedures. He / she shall undergo training and qualify from designated training centers for Eye Bank Technicians.

Eye Donation Counselor or Designate:

· Shall be responsible for counseling families at hospitals and coordinate with eye bank and hospital for retrieval of cornea.

· Shall also be responsible for awareness campaigns both within the hospital and outside the hospital.

Administrative Secretary cum telephone operator or Designate:

To perform the routine office work.

Training & Human Resource Development:

Each eye bank shall ensure that their personnel are adequately trained and their skills are constantly upgraded.

Medical Director:

The Medical Director shall undergo regular continuing education in Eye Banking and related issue. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

Executive Director & Eye Bank Manager:

The Executive Director and / or Eye Bank Manager shall undergo a refresher training module at an eye bank training center at least once a year. The eye bank shall provide written documentation of such attendance at the time

of eye bank inspection.

Eye Bank Technician:

Eye Bank Technician shall undergo a refresher training module at an eye bank training center at least

once a year. The eye bank shall provide written documentation of such attendance at the time of eye bank inspection.

Eye Donation Counselor:

Every eye bank shall have a specially designed counselling cum training module for the eye donation counsellor. This is necessary because the EDC deals with morbidity continuously. The frequency of such training & counselling sessions shall be at least once in four months. The eye bank shall provide written documentation of such attendance at the time of eye bank inspection.

HR Policy:

The eye bank training centre, eye bank and eye donation centre should have a HR policy for regular appraisal of performance, in house skill upgrading & training programs, recruitment policies, incentives for performance and counselling of all personnel.

Documentation:

Length of storage

All records shall be kept for a minimum of ten years (or comply with appropriate laws) from the date of transplantation/implantation.

Confidentiality

All eye bank records and communications between the eye bank and its donors and recipients shall be regarded as confidential and privileged.

Documents & Logbooks

The following documents, logbooks and records are to be maintained by EBTC, EB and EDCs:

Name of the document / log book EBTC EB EDC

- Donor initial information form
- Death Certificate / Eye Donor Medical Particulars
- Consent form
- Donor Information Sheet
- Serology Report
- Tissue Evaluation Report
- Haemodilution form
- Tissue distribution form
- Surgeons' adverse finding report form.
- Instrument cleaning log
- Sterilisation log
- Lab cleaning log
- Equipment cleaning log
- Equipment maintenance log
- Equipment calibration records
- Eye Bank Personnel training records & qualification certificate.

Registration:

Eye Bank Training Centres, Eye Banks and Eye Donation Centres should apply to their respective state government health authorities and get registered under Transplantation of Human Organs Act 1994.

They should perform their activities as prescribed in the applicable law like Transplantation of Human Organs Act until the registration is completed.

