DONOR MEDICAL ASSESSMENT

PURPOSE
The purpose of these standards is to set out the principles of donor selection, describing the minimum information required for donor risk assessment, and the sources for information, which should be documented as part of the donor record.

INFORMATION REQUIRED FOR DONOR RISK ASSESSMENT
- Donor’s identity and age;
- cause, time and circumstances of death;
- past and recent medical history;
- behavioural activity that increases the risk of transmissible diseases.

SOURCES OF INFORMATION
- medical records;
- attending medical and nursing staff;
- family members or other relevant persons close to the deceased;
- family doctor;
- physical examination of the donor;
- post-mortem report if available and timely (when autopsy is performed).

MICROBIOLOGICAL TESTING OF DONORS.
As a minimum sero-negativity for the following tests is required:
- HIV 1 and 2 antibody;
- HbsAg;
- HBc antibody;
- HCV antibody;
- Syphilis
Tests should be performed on a blood sample collected as soon as possible after death. The sample should be examined for haemolysis.
If the donor has received infusions within the last 48 hours, the volumes must be recorded and an algorithm applied to assess haemo-dilution.
Alternatively, an ante mortem blood sample taken before any transfusions or infusions, and up to 7 days before the donation, may be available for testing.
Heavy immunosuppression may invalidate serological antibody tests.

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DONOR AGE AND POST MORTEM TIME

Provided that corneas are examined to exclude those with inadequate endothelium, no upper donor age limit needs to be set, but other age-related corneal changes must be taken into account. The lower age limit is less certain and will depend on surgical demand.

It is recommended that corneal preservation occurs as soon as possible after death. All time intervals for each donor (death to enucleation and preservation) shall be recorded.

CONTRAINDICATIONS TO THE USE OF DONOR OCULAR TISSUE FOR TRANSPLANTATION

1 INFECTIONS:
   1.1 Rabies.
   1.2 Acquired immunodeficiency syndrome (AIDS / HIV).
   1.3 Active viral hepatitis (A, B, C).
   1.4 Seropositivity: HIV, HbsAg, HCV, syphilis (active syphilis (old infection=>seropositive testing))
   1.5 Behaviour leading to risk of contracting HIV, hepatitis B or C.
   1.6 Viral encephalitis or encephalitis of unknown origin, viral meningitis.
   1.7 Congenital rubella.
   1.8 Reyes syndrome.
   1.9 Tuberculosis (active disease or within first six months of treatment).
   1.10 Progressive multifocal leucoencephalopathy.
   1.11 Septicaemia.
   1.12 Jaundice of unknown aetiology
   1.13 HTLV 1 and 2 infection
   1.14 Active malaria
   1.15 Receipt of an organ transplant
   1.16 Recipient of postexpositional Rabies vaccine within previous 12 months
   1.17 Recipient of live vaccine within previous 12 months (e.g. Polio, Yellow Fever, Rubella, Measles, Mumps)
   1.18 Recipient of hemodialysis

2 UNKNOWN AETIOLOGY AND CNS DISORDERS:
   2.1 Creutzfeldt-Jakob disease and the following risk groups:
      ▪ Family history of CJD.
      ▪ Recipients of dura mater or brain/spinal surgery before August 1992.
      ▪ Recipients of human pituitary-derived hormones.
   2.2 Central nervous system diseases of unknown aetiology (e.g. multiple sclerosis, Alzheimer’s disease, other dementias.)
   2.3 Sub-acute sclerosing panencephalitis (slow infection caused by measles virus with symptoms resembling CJD)
   2.4 Chronic fatigue syndrome
   2.5 Death from unknown cause
3 MALIGNANCIES and PREMALIGNANCIES:
3.1 Leukaemia.
3.2 Lymphoma.
3.3 Myeloma.

4 EYE DISEASE AND OCULAR SURGERY:
4.1 Ocular inflammation (including known ocular involvement by systemic disease e.g. sarcoidosis, rheumatoid arthritis)
4.2 Congenital or acquired disorders of the eye, or previous ocular surgery that would prejudice graft outcome.
4.3 Retinoblastoma.
4.4 Malignant tumours of the anterior segment.
4.5 Receipt of a corneal, scleral or limbal graft

USE OF PRESERVED SCLERAL TISSUE
Donor medical assessment is the same as for corneas.

USE OF LIMBAL TISSUES FOR KERATO-LIMBAL-ALLOGRAFTS
Donor medical assessment is the same as for corneas.
Malignancies represent additional contraindications because the limbus is vascularised.

NOTES:
1 High risk behaviour includes:
   • having sex with someone who has (or thinks they have) AIDS or who is HIV positive
   • men having sex with another man
   • working as a prostitute
   • injecting drugs, even once
   • within the last 12 months:
     – having sex with someone who has participated in the above high risk activities
     – having sex with someone, of any race, living in Africa (except Morocco, Algeria, Tunisia, Libya or Egypt)
     – tattooing, acupuncture, ear or body piercing not professionally done (every 'ear-ring-wearer'=contraindicated)
   • imprisonment

2 Viraemia and viral meningitis are absolute contraindications. Bacterial forms of septicaemia or meningitis may be acceptable at the discretion of the eye bank Medical Director but only when the corneas are to be stored by organ culture. Additional microbiological testing is required.

3 Increased risk of CJD transmission.

4 Death from unknown cause is not a contraindication provided a post-mortem examination is pending and the result will be known before the tissue is transplanted.
APPENDIX

This appendix is meant as a resource for eye banks and competent national authorities. It summarise previously published peer-reviewed papers on possible disease transmission with a human corneal donor graft. The Medical SIG group will be happy to receive information on new or previous published papers not included in the list.

LITERATURE
Only original reports documenting transfer of disease from a corneal donor to a recipient are included.

1. INFECTIONS

Rabies
Human-to-human transmission of rabies virus by corneal transplant.
PMID: 368632 [PubMed - indexed for MEDLINE]

Two rabies deaths after corneal grafts from one donor.
Gode GR, Bhide NK.
PMID: 2901628 [PubMed - indexed for MEDLINE]

Transmission of rabies by corneal graft.
Javadi MA, Fayaz A, Mirdehghan SA, Ainollahi B.
PMID: 8776570 [PubMed - indexed for MEDLINE]

HIV
No reports

HAV
No reports

HBV

HCV
No reports
Congenital rubella.
No reports

Reyes syndrome.
No reports

Tuberculosis (active disease or within first six months of treatment).
No reports

Progressive multi-focal leucoencephalopathy (JC virus).
No reports

Septicemia
Donor-to-host transmitted Candida endophthalmitis after penetrating keratoplasty.
Schotveld JH, Rajmakers AJ, Henry Y, Zaal MJ.
PMID: 16160513 [PubMed - indexed for MEDLINE]

Pseudomonas aeruginosa endophthalmitis after penetrating keratoplasty transmitted from the same donor to two recipients confirmed by pulsed-field gel electrophoresis.
Oguido AP, Casella AM, Hofling-Lima AL, Pacheco SA, Bispo PJ, Marques F.
PMID: 21775545 [PubMed - indexed for MEDLINE]

Jaundice of unknown aetiology
No reports

HTLV 1 and 2 infection
No reports

Active malaria
No reports

Receipt of an organ transplant
No reports

2. UNKNOWN AETIOLOGY AND CNS DISORDERS

CJD
Letter: Possible person-to-person transmission of Creutzfeldt-Jakob disease.
Duffy P, Wolf J, Collins G, DeVoe AG, Streeten B, Cowen D.
Complications of keratoplasty.
DeVoe AG.
PMID: 1094832 [PubMed - indexed for MEDLINE]

[Manifestation of Creutzfeldt-Jakob disease 30 years after corneal transplantation]
Thiel HJ, Erb C, Heckmann J, Lang C, Neundörfer B.
PMID: 11146831 [PubMed - indexed for MEDLINE]

**Viral encephalitis or encephalitis of unknown origin, viral meningitis**
No reports
Comment: Reasonable as diagnosis of CJD is difficult

**Central nervous system diseases of unknown aetiology** (e.g. multiple sclerosis, Alzheimer’s disease, other dementias.)
No reports

**Sub-acute sclerosing panencephalitis** (slow infection caused by measles virus with symptoms resembling CJD)
No reports

**Chronic fatigue syndrome**
No reports

**Death from unknown cause**
No reports

3. **MALIGNANCIES**

**Leukaemia**
No reports

**Lymphoma**
No reports

**Myeloma**
No reports

4. **EYE DISORDERS AND PREVIOUS EYE SURGERIES**
Ocular inflammation (including known ocular involvement by systemic disease e.g. sarcoidosis, rheumatoid arthritis)

- HSV
Primary graft failure: a clinicopathologic and molecular analysis.
Cockerham GC, Bijwaard K, Sheng ZM, Hidayat AA, Font RL, McLean IW.
PMID: 11054337 [PubMed - indexed for MEDLINE]

Herpes simplex virus 1 transmission through corneal transplantation.
Remeijer L, Maertzdorf J, Doornenbal P, Verjans GM, Osterhaus AD.
Lancet. 2001 Feb 10;357(9254):442.

- CMV
The risk of cytomegalovirus transmission by penetrating keratoplasty.
Holland EJ, Bennett SR, Brannian R, Osborne JC, Goeken JA, Krachmer JH.
PMID: 2833856 [PubMed - indexed for MEDLINE]

- EBV
No reports

- VZV
No reports

- Acanthamoebae
Two red eyes and one asymptomatic donor.
PMID: 19932357 [PubMed - indexed for MEDLINE]

- Bacteria
No reports (organ culture)

- Fungi
No reports (organ culture)

Congenital or acquired disorders of the eye, or previous ocular surgery that would prejudice graft outcome.
No reports

Retinoblastoma.
No reports
Malignant tumours of the anterior segment.
No reports

Receipt of a corneal, scleral or limbal graft
No reports

REVIEW PAPERS
Only review papers related to disease transmission with are corneal graft are included.

Donor to host transmission of disease via corneal transplantation.
Gandhi SS, Lamberts DW, Perry HD.
PMID: 6452711 [PubMed - indexed for MEDLINE]

Diseases potentially transmitted through corneal transplantation.
O'Day DM.
PMID: 2677886 [PubMed - indexed for MEDLINE]

Transplanted infections: donor-to-host transmission with the allograft.
Gottesdiener KM.
PMID: 2658709 [PubMed - indexed for MEDLINE]

Review of the risk of HIV infection through corneal transplantation in the United States.
Caron MJ, Wilson R.
PMID: 8201168 [PubMed - indexed for MEDLINE]

Transplantation of corneal tissue from donors with diseases of the central nervous system.
Hogan RN, Cavanagh HD.
PMID: 8575171 [PubMed - indexed for MEDLINE]

Infectious disease transmission through cell, tissue, and organ transplantation: reducing the risk through donor selection.
Eastlund T.
PMID: 8520830 [PubMed - indexed for MEDLINE]
Creutzfeldt-Jakob disease via dural and corneal transplants.
Lang CJ, Heckmann JG, Neundörfer B.
PMID: 9849795 [PubMed - indexed for MEDLINE]

Risk of prion disease transmission from ocular donor tissue transplantation.
Hogan RN, Brown P, Heck E, Cavanagh HD.
PMID: 9894930 [PubMed - indexed for MEDLINE]

Transmission of viruses through corneal transplantation.
Robert PY, Adenis JP, Denis F, Ranger-Rogez S.
PMID: 16122153 [PubMed - indexed for MEDLINE]

Minimizing the risk of disease transmission during corneal tissue processing.
Lindquist TD, Miller TD, Elsen JL, Lignoski PJ; Policy and Position Research Subcom
mittee of the Medical Advisory Board of the Eye Bank Association of America.
PMID: 19421054 [PubMed - indexed for MEDLINE]

Donor selection, retrieval and preparation of donor tissue. Donor selection.
Borderie VM.
PMID: 19494634 [PubMed - indexed for MEDLINE]

Risk of Creutzfeldt-Jakob disease transmission by ocular surgery and tissue transplantation.
Armitage WJ