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## MINIMUM MEDICAL STANDARDS \*

### DONOR MEDICAL ASSESSMENT

#### PURPOSE

The purpose of these standards is to comment on the principles of donor selection, as laid down by the COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 describing the minimum information required for donor risk assessment and the sources of information that 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 (The European Directive does not require NAT testing for HIV, and there is no scientific evidence to suggesting that NAT testing is beneficial).
- HBsAg;
- HBc antibody (When anti-HBc is positive and HBsAg is negative, further investigations are necessary with a risk assessment to determine eligibility for clinical use. For example, a positive anti-HBsAg, or negative HB NAT test should allow the donor tissue to be used for clinical use);
- HCV antibody;
- Syphilis (A specific syphilis positive reaction does not necessarily require discard and the tissue could be transplanted on the basis of a thorough risk assessment. A thorough risk assessment is defined as a re-evaluation of all donor sources of information, with particular focus on transmissible diseases).

HTLV-I antibody testing should be performed for donors living in, or originating from, high-incidence areas (Caribbean Basin, Central and Southern Africa, South Japan, Central and South America, as well as localized areas of Iran and Melanesia), or with sexual partners originating from those areas or where the donor's parents originate from those areas.



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Blood samples must have been obtained just prior to death or, if not possible, the time of sampling must be as soon as possible after death and in any case within 24 hours after death, although it should be noted that there is no scientific evidence showing that blood samples obtained later than 24 hours after death turn out to be false negative.

If the donor has received transfusions or infusions within the last 48 hours, the volumes must be recorded and an algorithm applied to assess plasma dilution. Plasma dilution may not exceed 50% if the testing procedures have not been validated for such plasma. According to the EDQM "Guide for the quality and safety of tissues and cells for human application" [3rd Edition 2017, pages 86-88] the following formula can be used to calculate the respective plasma dilution:

Donor total plasma volume =  $0.04 \text{ [l/kg]} * \text{donor body weight [kg]}$

Infused colloids within 48h ante-mortem =  $\text{colloids}_{48\text{h}} \text{ [l]}$

Infused crystalloids within 1h ante-mortem =  $\text{crystalloids}_{1\text{h}} \text{ [l]}$

Total relevant infused volume =  $\text{colloids}_{48\text{h}} \text{ [l]} + \text{crystalloids}_{1\text{h}} \text{ [l]}$

Acceptable plasma dilution:  $\text{Total relevant infused volume} \leq \text{Donor total plasma volume}$

or

$(\text{colloids}_{48\text{h}} + \text{crystalloids}_{1\text{h}}) \text{ [l]} \leq (0.04 \text{ [l/kg]} * \text{body weight [kg]})$ .

Explanation: Donor body weight (kg) × 0.04 (l/kg) serves as an estimate of the donor total plasma volume. The infused volume of colloids (within 48 hours prior to death) and crystalloids (within 1 hour prior to death) is summarized. Their total volume must be less than the estimated donor plasma volume.

Eye banks may accept tissues from donors with plasma dilution of more than 50 % only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available.

The *ante mortem* blood sample should be taken before any transfusions or infusions, and up to 7 days before the donation.

As the treatment with immunosuppressive agents may invalidate serological antibody tests, a thorough risk assessment is recommended (re-evaluation of all donor sources of information, with particular focus on transmissible diseases). In case of uncertainty NAT testing for HIV, HBV and HCV might be helpful for a thorough risk assessment.

#### 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

The listed contraindications are an interpretation of the general criteria for exclusion, as given by Annex I, EC 17, 2006, with particular relevance to ocular tissues

- Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies;
- History of a disease of unknown aetiology;



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- Donors with malignant diseases can be evaluated and considered for cornea donation (not for donation of vascularized ocular tissues), except for those with retinoblastoma, haematological neoplasm (such as leukaemia, lymphoma, myeloma), and malignant tumours of the anterior segment of the eye (i.e. primary tumours such as conjunctival intraepithelial neoplasia, squamous cell carcinoma or malignant melanoma as well as metastasis in the anterior ocular segment from other primary malignant tumours). In the case of donors with malignant diseases and a potential risk of metastasis formation in the anterior ocular segment, a thorough slit-lamp examination of the globe or the corneo-scleral disc focused on possible metastasis must be undertaken in the eye bank;
- Risk of transmission of diseases caused by prions. This risk applies, for example, to:
  - a) people diagnosed with Creutzfeldt–Jakob disease, or variant Creutzfeldt-Jacob disease, or having a family history of non-iatrogenic Creutzfeldt-Jacob disease;
  - b) people with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin, such as Alzheimer’s Disease, multiple sclerosis, amyotrophic lateral sclerosis;
  - c) recipients of hormones derived from the human pituitary gland (such as growth hormones) and recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).
- Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral (such as rabies), fungal or parasitic infections, or significant local infection in the tissues and cells to be donated. Donors with bacterial septicaemia (except for encephalitis and meningitis) may be evaluated and considered for eye donation but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue;
- History, clinical or laboratory evidence of HIV or AIDS, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections;
- History of chronic, systemic autoimmune and/or inflammatory disease that could have a detrimental effect on the quality of the tissue to be retrieved;
- Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor social history (e.g. intravenous drug abuse, sexual promiscuity), travel and exposure history and local infectious disease prevalence; in this context according to the Standards for the surveillance and epidemic intelligence actions of the European Centre of Disease Control it is important to investigate travel in high-risk regions when checking social anamnesis with regards to new or emerging communicable diseases such as the Ebola virus, Zika-virus etc. To look for a specific disease index for a country the UK Blood Services Geographical Disease Risk Index for example lists the current disease risks for specific countries ([www.transfusionguidelines.org](http://www.transfusionguidelines.org)).
- Presence on the donor’s body of physical signs implying a risk of transmissible disease(s), such as bruises, lacerations, scars, piercing, needle tracks not compatible with recent clinical history, fresh tattoos that may hide parenteral drug use, and signs of transmissible diseases such as Kaposi sarcoma, swollen lymph nodes, skin rashes, Jaundice of unknown aetiology, should be interpreted in the context of donor medical and social history;
- Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may affect the quality of the ocular tissue, or may be transmitted to recipients in a dose that could endanger their health;
- Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist;
- Transplantation with xenografts;
- Additional exclusion criteria for deceased child donors;
- Any children born from mothers with HIV infection or that meet any of the exclusion criteria described above must be excluded as donors until the risk of transmission of infection can be definitely ruled out:



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- a) Children aged less than 18 months born from mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have been breastfed by their mothers during the previous 12 months, cannot be considered as donors regardless of the results of the analytical tests;
- b) Children of mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have not been breastfed by their mothers during the previous 12 months and for whom analytical tests, physical examinations, and reviews of medical records do not provide evidence of HIV, hepatitis B, hepatitis C or HTLV infection, can be accepted as donors;
- Eye diseases and ocular surgery: congenital or acquired disorders of the eye (e.g. herpetic keratitis), or previous ocular surgery, that would prejudice graft outcome (e.g. corneas with previous refractive surgery, or stromal scars, may be acceptable for posterior lamellar keratoplasty).

#### USE OF PRESERVED SCLERAL AND LIMBAL TISSUES FOR KERATO-LIMBAL-ALLOGRAFTS

All the donor medical assessment criteria for corneas apply but, as sclera and limbal tissue are vascularized, malignancies and infections represent additional contraindications as they do for vascularized non-ocular tissues.

#### LITERATURE

The following literature review is meant as a resource for eye banks and competent national authorities. It summarises papers on donor selection and screening, disease transmission and risk assessment.<sup>†</sup>

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<sup>†</sup> A useful collection of papers on adverse events and reactions for ocular tissues can also be found on the [www.notifylibrary.org](http://www.notifylibrary.org) database (The Global Vigilance and Surveillance Database for Transplantation and Assisted Reproduction).



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