

Donor Screening for TSE: Safety and Supply of Corneal Transplants

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EBAA Medical Standards

- ◆ Developed by EBAA Medical Advisory Board
- ◆ Standards for accredited banks
- ◆ Scientifically based
- ◆ Insure safety of eye bank personnel
- ◆ Insure efficacy and safety of eye tissue for human transplantation

EBAA Medical Standards

- ◆ Require donor screening to construct an adequate donor profile
- ◆ Donor profile determines the suitability of tissue for human transplantation
- ◆ ALL donors must be screened
 - Includes tissue obtained via legislative consent

Donor Screening Must Include*

- ◆ Identification of the donor
- ◆ Serologic testing
- ◆ Physical assessment of the donor
- ◆ Tissue evaluation
- ◆ Donor history evaluation
- ◆ Medical director oversight

*EBAA Medical Standards

Donor History Evaluation*

- ◆ All available records must be reviewed by qualified personnel, to include information from at least one of the following:
 - Pathologist's or medical examiner's physical assessment or death report
 - Medical examiner's investigative report
 - Medical record or hospital chart
 - Treating physician interview
 - Family interview

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TSE Screening: Exclusions*

- ◆ Creutzfeldt-Jakob disease (CJD)
- ◆ Family history of blood relative with CJD
- ◆ Recipients of human pit-hGH from 1963-1985
- ◆ Recipients of non-synthetic dura mater grafts
- ◆ Progressive encephalopathy
- ◆ Encephalitis: active viral or of unknown origin

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TSE Screening: Exclusions*

- ◆ Death of unknown cause
- ◆ Neurologic disease of unestablished diagnosis
- ◆ Progressive multifocal leukoencephalopathy
- ◆ Subacute sclerosing panencephalitis
- ◆ Reyes syndrome
- ◆ Rabies

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TSE Screening: Effectiveness

- ◆ U.S.A.: 1 case reported (Duffy, NEJM 1975)
- ◆ Led to establishment of EBAA screening criteria
- ◆ >600,000 cornea transplants performed since, with no additional reported cases in the U.S.A.
- ◆ International reports - "presumed" transmission
 - 1 case Germany (Heckmann, J Neurol Neurosurg Psych, 1997)
 - 1 case in Japan (Uchiyama, Dementia, 1994)
- ◆ 1 donor in U.K., 3 recipients disease-free at 2 years (Hogan, Cornea, 1999)

Can TSE Screening Be Improved?

- ◆ Brain biopsy?
 - Time limitations would eliminate all corneal tissue
- ◆ Donor history screening for specific symptoms?
 - Can not detect asymptomatic cases
 - At 100% sensitivity & 90% specificity, >36,000 donors would be incorrectly excluded for each CJD donor correctly excluded. (Kennedy)
- ◆ Donor medical history interview in legislative consent cases?

TSE Screening & Legislative Consent

- ◆ Tissue procured via legislative consent comes from a younger donor population. (Kennedy)
- ◆ Younger donors are less likely to harbor TSE. (Kennedy)
- ◆ The risk of preclinical, symptomatic and diagnosed CJD among donors obtained via legislative consent is 40% less than the risk of preclinical disease alone among all other donors. (Kennedy)

TSE Screening & Legislative Consent

- ◆ There is no scientific basis for concluding that a donor medical history interview (with a relative, household member, treating physician or individual with an affinity relationship) would reduce the risk of TSE in donors whose ocular tissues are procured under legislative consent. (Kennedy)

Legislative Consent & Cornea Supply

- ◆ The number of donors obtained via legislative consent would be reduced by as much as 90% if a donor medical history interview were required.
- ◆ Approximately 5-10% of donors are obtained through legislative consent in the U.S.A.
- ◆ There are major local variations in the percentage of transplantable corneas obtained via legislative consent.

Legislative Consent & Cornea Supply

- ◆ Percent of transplantable corneas obtained via legislative consent*:

*estimate, 2000

Legislative Consent & Cornea Supply

- ◆ Requiring a medical history interview for tissue obtained via legislative consent would create local shortages of corneal tissue in several major metropolitan areas.
- ◆ Local shortages are not easily remedied by importation of tissue from other U.S. eye banks - or by substituting tissue that is currently exported.
- ◆ EBAA members do not import foreign tissue.

TSE Screening: Conclusions

- ◆ Requiring a donor medical history interview in legislative consent cases would:
 - Eliminate most donors obtained via that route
 - Create local shortages of corneal tissue
 - Eliminate scheduled surgery in some areas
 - Increase the number of patients waiting for corneas
 - Possibly, increase the risk of TSE due to an increase in the overall age of the donor pool (Kennedy)

TSE Screening: Conclusions

- ◆ Screening donors for specific symptoms would markedly reduce the corneal supply without increasing the safety of the donor pool. (Kennedy)
- ◆ Requiring a donor brain biopsy would eliminate most or all corneas suitable for transplantation.
- ◆ If there is a need to improve TSE screening, new tests are needed.