Donor selection in Denmark. Recent developments.

Jesper Hjortdal & Kim Nielsen

The Danish Cornea Bank
Århus
EU-Directive 2004/23/EF

- EU-Directive 2004/23/EF with appendices defines new regulations for transplantation of corneal tissue

- Member states may add other regulations

- The directive was implemented in Denmark in 2007
Denmark

- Supplemental NAT-testing of the donor for HIV, HBV, and HCV have been made mandatory
HIV Transmission with corneal tissue?

- No published reports of HIV transmission by cornea tissue (not possible)

- HIV was not transmitted to any recipient of transplanted donor corneal grafts from 9 HIV-positive donors (Simonds RJ. HIV transmission by organ and tissue transplantation. AIDS. 1993; 7 Suppl 2: S35-8)
L'age-Stehr et al. 1985 Transmission of HTLV-III (the old name for HIV-1 virus) from 3 donors to 4 kidney recipients.

#1527

Neumayer et al.
1987
Germany
They conclude that HIV and HTLV can transmit by organ transplantation. This article is sometimes cited in the literature but it is not relevant in respect of cornea transplantation!

#1549

Schwarz et al.
1987
Holland/Germany
2 kidney recipients died from HIV. Archived blood from the two donors was tested positive for anti-HIV (ELISA). 3 corneas recipients were tested negative (3 years after grafting) and the forth recipient refused testing.

#1552

Pepose et al.
1987
United States
2 cornea donors were retrospectively found HIV positive (ELISA). None of the 4 cornea recipients had seroconverted (1 year after grafting).

#1100

Conway & Insler
1987
USA
Questionnaire investigation of EBAA eye banks on screening (Elisa) cornea donors for HIV antibodies (0.68 %) and HBV antigens (1.33%).

#1526

Simonds et al.
1992
United States
4 organ recipients showed different signs of HIV. The mutual donor had been tested negative for HIV but archived spleen tissue the same donor was tested positive. 2 cornea recipients were tested negative.

#1210

Simonds
1993
United States
Review. The 9 discussed cornea cases originate from #1526, #1549 and #1552.

#1523

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HBV Transmission with corneal tissue?


- Donor serology testing was not performed before grafting

- Both patients recovered
HCV Transmission with corneal tissue?

- No published reports of HCV transmission by cornea tissue
Iatrogenic CJD

- No evidence of transmission
- Recipient cases not more common than would be expected by chance
Rabies

- Transmission documented in several papers
- Lethal outcome
Syphilis

- Transmission not shown (not possible)
Risks

- 1 : 20,000,000 risk for HBV transmission with a corneal graft without NAT testing

In comparison:

- 1 : 10,000 for personal injury while being transported in a car to pre-op and post-op visits (1,000 km) related to a keratoplasty procedure
Price

- 1 : 2.000.000 without testing
- 1 : 20.000.000 with HBV serology testing

Price for avoiding 1 HBV transmission is
10.000.000 * 100 Euro =

- 1.000.000.000 Euro
Conclusion

- The possible health benefits of NAT-testing corneal donors in Denmark are negligible

- The economical expenses to avoid possible transmission are astronomical

- But in Danish NAT testing of corneal donors is still mandatory
Donor selection in Denmark

- Opting-in
- Multi-organ donors
- Donation in conjunction with autopsy
- Donation from deceased patients in hospital
How to obtain more donors

- Increase number of procurement sites
- Educate staff (certification by national competent authority)
One Bank –
Many procurements institutions
Education of procurement staff

- Technicians on Pathology departments
  - Legislation
  - Physical examination
  - Enucleation
  - Paper work
Contracts with Pathology departments

- **Anamnestic indicators:**
  - journal record
  - in few cases also interview with GP

- **Physical examination:**

- **Biochemical indicators:**
  - Serology
  - PCR-based techniques
2009

- 82 donors (164 corneas)
- Autopsy 5
- Multi organ donation 17
- Donor register 55
- Relatives (not organ donor) 7
Conclusion

- Collaboration with pathology departments all over Denmark
- Donor assessment by pathologist
  - Anamnestic indications
  - Physical indications
- Rather strong search for biochemical markers for HIV, HBV, HCV