SaBTO

• Advisory Committee on the Safety of Blood, Tissues and Organs
Post Transplant
TWIN GIVES KIDNEY TO HIS BROTHER

Operations on Leith men

Surgeons at Edinburgh Royal Infirmary said yesterday that they were "very pleased" with the progress of twin brothers who, on Sunday, underwent a kidney transplantation operation. This is the first time such an operation has been performed in Great Britain and Dr S. G. M. Francis, medical superintendent, said at a Press conference: "I think the recipient has a sporting chance of getting away with it"
MSBTO

- Department of Health
- Safety gradient
- Blood
- Tissues
- Organs
SaBTO

SHOT 7th July 2008
• The Committee will advise Ministers of the UK Government and the Devolved Administrations as well as UK Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation. Its remit includes providing independent advice on:

• the microbiological safety of gametes and stem cells, in liaison with the relevant regulatory authorities; and

• risk management options for Ministers and UK Health Departments to consider
Dr Keshwar Baboolal
Professor Peter Braude
Professor John Cairns
Professor John Dark
Professor Ian Franklin
Dr George Galea
Mrs Catherine Howell
Professor Dierdre Kelly
Dr Harpreet Kohli
Dr Eithne MacMahon
Professor Joanne Martin
Mr Elwyn Nicol
Dr Tyrone Pitt
Dr Michael Potter
Professor Hamish Simpson
Professor Richard Tedder
Professor Marc Turner
Dr Hester Ward
Dr Anthony Warrens

Risk Assessment Manager/Communicator
IVF/Fertility/Stem Cell Specialist
Health Economist
Solid Organ Transplant Surgeon
Medical Director from Blood Services
Blood/Transplant Service Manager
Nurse
Physician
Epidemiology/Public Health
Microbiologist/Bacteriologist/Virologist
NHS Management
Patient Representative
Microbiologist/Bacteriologist/Virologist
Haematologist
Orthopaedic Surgeon
Microbiologist/Bacteriologist/Virologist
Haematologist
CJD Expert
Immunologist
• Establish, by July 2008, a framework to underpin a consistent approach to safety evaluation.

• Advise on risk reduction measures to minimise the potential transmission of vCJD by transfusion and transplantation.

• Update the existing Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in transplantation in the next reporting year.
• Review the appropriateness of current blood, tissue and organ donor selection criteria in light of advances in screening and treatment of infectious agents
• Advise on outstanding issues arising from the MSBTO bone and tissue subgroup
• Provide advice and recommendations on measures to reduce the risk of transmitting bacterial and other infections via blood transfusion
• Provide advice and recommendations on other safety issues as the need arises
What is vCJD?

- Human form of BSE, first described in 1996
- A transmissible spongiform encephalopathy (TSE), fatal within 18 months
- Peak age at onset is 20s
- The infectious agent is a prion - no DNA
- No treatment as yet (MRC trial)
# vCJD worldwide
### April 2008

<table>
<thead>
<tr>
<th>Country</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
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<tr>
<td>France</td>
<td>22</td>
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<tr>
<td>Republic of Ireland</td>
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<td>USA</td>
<td>3</td>
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<tr>
<td>Netherlands</td>
<td>2</td>
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</tbody>
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Potential expansion of vCJD epidemic by transfusion and surgical instruments

BSE  vCJD infection  incubation  death

(after M Busch)

(10-20 years)
vCJD is transmissible by transfusion

- Mice, hamsters, sheep, primates -
  - 50-70% transmission rates
- Humans - 4 probable transmissions
  - All 4 by red cells before LD (3 donors)
  - Donations 17-40 months before symptoms
  - 3 recipients developed symptoms 6-8 years after transfusion (1 found at PM)
  - >60 other components traced to recipients, of whom 30 survived > 5 years
  - Transmission rate therefore 4/30 in >5 year survivors
- No transmissions by platelets, FFP, plasma products, stem cells, tissues or organs
Overall risk driven by the numbers of healthy carriers

- Considerable uncertainty of numbers
- Previous survey of 12,000 tonsils
  - 1 in 4000-10,000 – used by SEAC.
- Ongoing surveys
vCJD prions in blood - great uncertainties

- Little is known about the level, distribution, and timing of development of infectivity in human blood.
- All assumptions have wide ranges.
- Animal evidence: *infectivity in plasma and leucocytes*; not in ‘pure’ red cells or platelets.
vCJD

- Measures already being taken (plasma, exclusion of those transfused etc)
- Better use of Blood
- Filtration
- Screening tests
- Consent?
False positives are a potential problem even if test 99% specific

UK would have 20,000 false pos donors/year-
therefore need second ‘confirmatory’ test
Consent for Transfusion

- Not just vCJD
- Difficult to put in to practice?
- Right to know?
- We consent for other (lesser) interventions
Potential risks from tissues and organs

- brain and posterior eye: high-range
- ocular tissues: mid-range
- bone: lower range
- tendon: lower range
- heart valves: lower range
- amniotic membrane: lower range
- skin: lower range
- haemopoietic stem cells: lower range
- transplanted organs: lower range
vCJD risk reduction steps—how decisions will be made

• First consideration of all options by SaBTO 29\textsuperscript{th} April 2008-
• For each option, consider effectiveness, cost, feasibility, effect on supply
• Possibility of implementation for some recipients only eg children
• Further review at next meeting
• Open meeting in autumn
• Final decisions will be by Health Ministers in all Health administrations.
European donor rates (2006)

Country

- Greece: 7.2
- Switzerland: 10.7
- Denmark: 11.2
- Slovak R: 11.8
- Netherlands: 12.3
- UK: 12.9
- Poland: 13.0
- Croatia: 13.5
- Sweden: 15.1
- Germany: 15.3
- Norway: 16.7
- Hungary: 17.7
- Latvia: 18.7
- Finland: 20.7
- Italy: 21.7
- US: 22.6
- France: 23.2
- Spain: 33.8

Donors per million population (pmp)
Donor Card
I would like to help someone to live after my death.
Let your relatives know your wishes and keep this card with you at
Organ donation and transplantation