

The Risk of nvCJD in Recipients of Hematopoietic Cell Transplants and the Impact of Deferring Donors from the UK

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Three Useful Sources of Hematopoietic Cells for Transplant

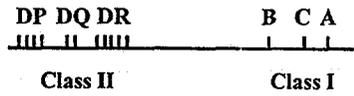
- Bone Marrow
- Peripheral Blood Stem Cells (PBSC)
- Umbilical Cord Blood

Administered total cell doses are between 10^8 and 10^{10}

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HLA Matching is Required for all Hematopoietic Cell Transplants

The HLA genes are clustered on the short arm of Chromosome #6



Only 25 – 30% of persons have a matched sibling donor

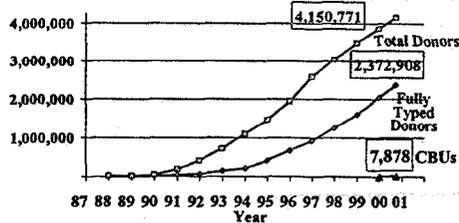
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The Unrelated Donor Storehouse

- ~ 7 Million bone marrow and stem cell donors in 48 registries
 - Only 53% HLA-A, -B & -DR typed
- ~ 55,000 Cord blood units in 21 cord blood banks
 - Virtually all HLA-A, -B & -DR typed

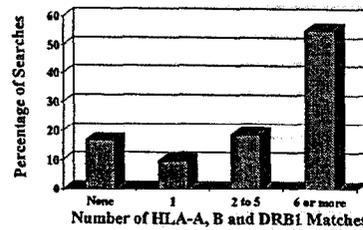
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National Marrow Donor Program Stem Cell Donors, September 30, 2000



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Likelihood of Matching Donors for 56,653 Patient Searches: July 2000



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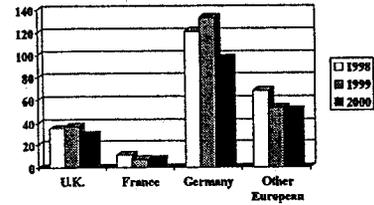
NMDP Unpublished Data

Additional Factors Considered in Donor Selection

- Donor age
- Donor size
- Donor sex
- Donor race
- Donor CMV serology
- Etc.

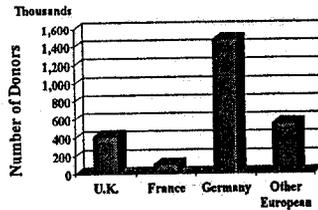
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Donors from Europe Providing HSC for U.S. Patients: 1998 - 2000



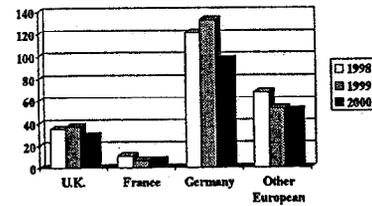
January 2001 NMDP Unpublished Data

Donors Registered in Europe, December 2000



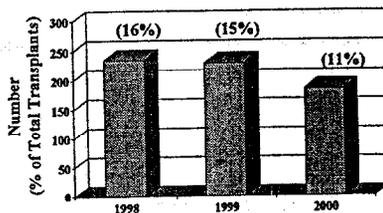
January 2001 NMDP Unpublished Data

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The Impact of Deferral upon U.S. Patients: Conclusions

- Deferral of European HSC donors would likely prevent some patients from proceeding to transplant.
- Other patients might still proceed to transplant, but with second choice donors.
- The numbers of patients affected depends upon the extent of deferral.

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Weighing Risk vs. Benefit

- **Unsuitable donors may still be used if -**
 - **There is an urgent medical need**
 - **A biohazard label is affixed**
 - **There is documentation that -**
 - **The transplant physician was notified**
 - **The physician accepted the product**
 - **The physician has agreed to counsel the patient**
 - **The physician has agreed to obtain consent**

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Summary

- **HSC donors are matched with recipients primarily by virtue of HLA type.**
- **Many potential recipients have few donors from which to choose.**
- **Elimination of some or all European donors from consideration would have a negative impact on U.S. patients.**
- **The patient and the physician may be best positioned to balance risk vs. benefit**

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