

Transmissible Spongiform Encephalopathy Advisory Committee

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Introduction

The purpose of my appearance before this committee is to request that the members of this committee give consideration to the use of a more specific risk based criteria for human sperm and egg donors than is currently in the FDA guidelines. It is the considered opinion of experts in human reproduction that the imposition of the guidelines developed for protection of blood donation is inappropriate for sperm and egg donors. This has had a negative impact on the availability of donor eggs and sperm. While many people may dismiss this effect as trivial, for those of us who are responsible for the recruitment of reproductive tissue donors, it has had a detrimental effect on sperm donor programs. The California Cryobank, where I serve as medical director, has lost about 20 donors this year due to the FDA guidelines for residence in the UK or in a European country. This represented about 13% of our active donors which had a material detrimental effect. It is our contention that the guidelines as currently written serve only to restrict reproductive choices of American women and do little or nothing to reduce the actual risk of vCJD.

Sperm banking, a brief overview

In a survey conducted by the American Association of Tissue Banks in 2005 there were about 80,000 vials of donor semen distributed for insemination. The number of recipients was approximately 20,000. The total number of individual sperm donors was about 1700.

In our program only about 2% of the initial donor applicants eventually become semen donors. There are many reasons for this very low retention rate. Each additional test or requirement causes some incremental loss. Based on discussions with other program directors all of us are having increasing difficulty in the recruitment and the retention of sperm donors.

Nearly all donor inseminations are intrauterine which requires the removal of the seminal plasma. Density gradient methods also remove leucocytes and most non-motile sperm. The typical biomass of a sperm sample prepared for intrauterine insemination is on the order of about 0.2-3 ml. This is only a fraction of the original ejaculate where the volume is typically 3-4 ml. Thus the final product represents only about 1/10th of the total ejaculate. Nearly all of the seminal plasma and most of the leucocytes have been removed further reducing potential risk. National standards of practice call for the rejection of a semen specimen that contains greater than 1M WBC/ml.

vCJD risk assessment by donor semen

In an attempt to evaluate this risk, David Mortimer and Chris Barratt reviewed the published literature on this subject and conducted a survey of 104 internationally recognized experts on prion disease or donor sperm banking. They concluded that the risk of transmission of vCJD is negligible in the opinions of experts and cited the following observations in support of their conclusion:

1. No evidence for sporadic CJD between spouses.
2. No evidence for sexual transmission of any TSE in any species, not even BSE by known infected bulls.
3. No transmission of familial CJD between spouses, and no disease in offspring unless they were mutation carriers.
4. The peak of vCJD is now past.
5. The PrP molecule in spermatozoa seems to be missing its C-terminus, reducing its ability to convert to the PrP^{sc} isoform.
6. Equivalent screening criteria to those employed in the UK for blood donors would essentially eliminate all individuals who were at risk for other forms of CJD.
7. The biomass inseminated during donor sperm insemination is only a fraction of an ejaculate per treatment cycle compared with normal sexual relationships.
8. The use of only washed sperm prepared by density gradient methods would further substantially reduce potential risk by the removal of seminal plasma and residual leucocytes.

Conclusion

It is my belief and those of more than 100 international experts, that the actual risk of vCJD in sperm and egg donors is very remote. Indeed a number of experts in prion disease are much more adamant about the absence of risk. We conclude that there is no plausible evidence to support the exclusion of sperm donors solely because they have lived for more than 5 years in a European country. The adoption of exclusion criteria similar to that employed in Canada or proposed for the European Union would be more than adequate to contain the theoretical risk.

References

Mortimer D and Barratt CLR. (2006) Is there a real risk of transmitting variant Creutzfeldt-Jakob Disease (vCJD) by donor sperm insemination? IN PRESS in *Reproductive Biomedicine Online*, 13 September 2006

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