

BSE

HPA Centre for infections

Report of Seminar on Ethical and Social Aspects of Testing for vCJD

It may be possible to test for the presence of traces of vCJD in blood samples. Blood donations would be screened. If so, what should be done to inform the potential donor?

The seminar concluded:

- The management of positive results for vCJD should be the same as for any disease.
- Current practice includes no right to opt out of such information; potential donors found to be reactive to blood tests for vCJD should therefore be informed of their test result. The wording on the consent form is *"I understand that if my donation gives a positive result for any of [the listed] tests I will be informed and asked to attend for further confirmatory tests and advice."*
- Individuals should be informed in advance that their blood will be tested.
- They should be told of the risks in their population group and be prepared for what would be done if a positive result was obtained. Such risks could be researched using unlinked testing.
- Long term monitoring of reactive donors should be offered.
- Before and during the early stages of uncertainty about test results further consultations with the insurance industry should aim to obtain clear agreement about how applications and premiums (and existing policies) may be affected by testing (positive and negative) both currently, and in the future.
- There is an ethical imperative to conduct scientific studies that will reduce the uncertainty of both positive and negative test results, and improve knowledge of prognosis for individuals who test positive.

Comment

vCJD transmission by blood donation from asymptomatic people is thought to have occurred more than once and is believed to present as high a risk of disease propagation as does the residual prevalence of BSE in cattle (less than 1 in a million). Screening of blood samples is essential if this risk is to be eliminated; filtering to remove prions from all donated blood may not work as well as disposing of tainted blood.

It is standard practice to undertake a repeat test (in duplicate) on any sample which is reactive in an initial automated test. Those donations found reactive in this repeat testing do not enter the blood supply and undergo confirmatory testing. It is essential that the confirmatory test is very accurate. As yet, such testing is not available.

A positive blood test could be false positive or may have no outcome meaning for the individual concerned:

- Any test of vCJD in blood or other tissues would be biased towards sensitivity rather than specificity; the consequences of missing a case could be fatal and this would be unacceptable.
- At this stage no-one knows the probability of conversion from a positive blood test to full blown disease.

The consequences of both false positive and false negative blood tests could be very costly indeed, as could inaccurate information about tests. Not knowing the likely outcome of a positive test is not likely to be a bar to the test being undertaken.

If filtering of prion proteins becomes practicable there may be less urgency to introduce blood tests. The degree of effectiveness of filtering in preventing disease transmission is not yet known.