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[Home](#) » [Opinion](#) » [Guests](#) » DoH goes for 'do nothing' option on tests for vCJD

[«Previous article](#) | [Next article»](#)

## DoH goes for 'do nothing' option on tests for vCJD

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*The IBTS has called on the Department of Health to re-establish an expert advisory group on vCJD to safeguard the blood supply, reports **Dara Gantly***

The Department of Health believes that a number of 'significant issues' need to be addressed before it can consider funding a new test for variant Creutzfeldt Jakob disease (vCJD).

An investigation by Irish Medical Times has revealed that Chief Medical Officer Dr Tony Holohan believes the Department has not received enough scientific evidence on a number of key issues to be in a position to make an adequate assessment of whether prion testing or prion filtration should be adopted to safeguard Ireland's blood supply.

The Irish Blood Transfusion Service (IBTS) submitted a detailed 'options appraisal paper' to the Department in April on the possible avenues open to the Minister for Health on the issue. These include: doing nothing; testing all donations; filtering all donations; filtering blood for younger recipients; combined filtration and testing; or filtering all red cells for children this year until the picture around testing becomes clearer. The cost of these options range from zero (doing nothing) up to E75 million over five years. The 'doing nothing option' won out.

### **Robust decision making**

In a letter from the IBTS to Minister Mary Harney the previous month, Chairperson Maura McGrath said the proposals on prion filtration of blood components and a test for vCJD would require 'robust decision making on the part of the Minister'. However, the Department has informed IMT that more detailed data and documentation on the effectiveness of the different technologies is still required, as well as more information on possible negative impacts, including the potential for 'false positive' individuals and a decrease in blood donation levels.

Along with the substantial cost of adopting the technologies — which the IBTS says it cannot meet within its current resources — prion testing may well cause donor distress and loss of donations due to difficult-to-resolve false positives. With no effective treatment or cure for vCJD, there is no diagnostic or prognostic value for an individual in knowing that one has the disease. Filtering, meanwhile, reduces the red cell content of blood units by 20 per cent, the clinical significance of which remains unclear.

The IBTS has 'urgently' called on the Minister to re-establish the vCJD Advisory Committee, set up when the Bovine Spongiform Encephalopathy (BSE, or 'mad cow' disease) epidemic first emerged in the UK. The Irish independent expert group, chaired by UCD's Prof Bill Hall, has not met since January 2006.

Speaking to IMT, IBTS CEO Andrew Kelly said: "There needs to be

an objective group to look at information that we submit — another voice of advice to the Minister.” However, the Department has rejected the request, despite the IBTS informing the Minister and her Secretary General Michael Scanlan that it was necessary to have such a ‘competent resource’ available to the Department.

While no other country has yet adopted either prion testing or filtration, it is possible that the UK and France, the other two countries most at risk from vCJD, will make a decision later this year. The filter is already in use in clinical studies in Ireland and the UK where it is performing satisfactorily to date and could be now more extensively deployed.

IBTS Medical and Scientific Director Dr Willie Murphy told IMT that use of the filter has been examined as part of a safety study in 20 patients from Cork, and a further hundred units are being transfused in Cavan General Hospital, where the system is in routine use.

“We need some more experience in paediatrics, so we plan to use it at Crumlin Hospital, probably starting next month,” Dr Murphy explained. He added that while some ‘caution’ was needed to ensure safety before rolling it out to 100,000 people a year, the IBTS was ready to do so.

Variant CJD, a fatal neurodegenerative disease, is the human form of BSE. The most likely cause is exposure to the BSE agent, most plausibly due to dietary contamination by affected bovine central nervous system tissue. While vCJD transmission by transfusion is very unlikely in Ireland, the risk is not zero.

Over the past 10 years, the IBTS has taken measures to try to offset any risk of transmitting vCJD from blood transfusion, including no longer accepting donations from people who have spent one year or more in the UK between 1980 and 1996.

### **Replacing cryoprecipitate**

It has also: deferred people who have had a blood transfusion in the past; implemented leucodepletion of red cells, platelets and plasma products; replaced plasma for clinical use from Irish donors with virus inactivated plasma from the US; and is currently replacing cryoprecipitate (made from Irish plasma) with fibrinogen concentrate made from US plasma.

The scale of the threat of vCJD, both from diet and blood transfusion, has diminished over the past decade, and any threat that remains is much smaller than once feared. Nevertheless, the IBTS believes some risk remains, and although this is likely to be small, the Service says it is important to maintain its ‘highly proactive stance in relation to this disease’.

Documents obtained through the Freedom of Information Act reveal that the IBTS Board, at its meeting on February 17, received a presentation from its Director of Testing, Dr Joan O’Riordan, on the current state of tests for vCJD. She explained that the best estimate was that there could be one or more infectious donors in the donor population — however there may well be none.

Leucodepletion — the removal of white blood cells from a blood component — may well have been effective in preventing transmission. However, Dr O’Riordan said the IBTS could not be certain of this. An infectious donor in the platelet apheresis panel could be ‘catastrophic’ if leucoreduction hasn’t worked. While this was extremely unlikely, it would be ‘an intolerable risk’ if a feasible test was developed.

Almost a decade has elapsed since the last known transmission of the disease happened in the UK, suggesting that either leucoreduction may be effective in preventing transmission, or that the number of infectious asymptomatic donors is small. However, as experts believe

that vCJD can be asymptomatic for about 10 to 16 years, there is no accurate way to determine either how many people could currently be harbouring the disease or the magnitude of future cases.

The incidence of vCJD in Ireland is second to that of the UK, and ahead of France.

Since 1996, a total of 208 patients from 11 countries have been identified. As of June 2008, cases have been reported from the following countries: 167 from the UK (1 per 350,000 population), 23 from France (1 per 3 million), four from Ireland (1 per million), three from the US, three from Spain, two in the Netherlands, two in Portugal, and one each from Canada, Italy, Japan, and Saudi Arabia. Two of the three US cases, two of the four cases from Ireland and the single cases from Canada and Japan were likely exposed to the BSE agent while residing in Britain.

So what are other countries doing? Last month (July 17), the NHS Blood and Transplant (NHSBT) authority in Britain awarded tenders to two companies — Amorfix Life Sciences and Prionics — to supply prion testing of blood donations. Due to the new and still emerging technologies, the NHSBT said it required suppliers to submit their systems for independent evaluation of performance.

This evaluation will initially assess the specificity of the assay on 10,000 stored (frozen) plasma samples from blood donations from the UK and the United States. One would not expect to find any positive vCJD in the US samples.

A spokesperson for the NHSBT told IMT that the tender related to evaluation only, and that the decision to roll out this technology would be taken by the UK Department of Health, which is guided by the advisory committee on the Safety of Blood Tissues and Organs (SaBTO).

On prion filtration, reports have suggested that SaBTO believes implementing this would not be cost-effective under the majority of scenarios modelled for risk. The UK government is expected to decide in October whether or not this method should be introduced.

In June, Amorfix also announced that it had tested 20,000 blood donations in France — the next country hardest hit by vCJD — using its EP-vCJD blood screening test as part of a large-scale study to demonstrate the feasibility of routine testing of blood donations.

#### **100 per cent specific**

At the UK specification of a required sensitivity of 1:100,000 dilution of vCJD brain, the company said its test was 100 per cent specific with no false positive samples on repeat testing. The test performed five times better than required as it was still 100 per cent specific at a sensitivity of 1:500,000 dilution of vCJD brain.

“France has taken a leading role in assessing the feasibility of testing routine blood donations for vCJD by establishing the Amorfix test in two major blood transfusion centres,” explained Dr George Adams, CEO of Amorfix. “The Amorfix test continues to demonstrate its readiness for use by high-risk nations to conduct prevalence studies to assess the safety of their blood supply.”

The IBTS is working closely with the UK and is planning on the basis that a test will become available this year. IBTS CEO Andrew Kelly believes the position should become clearer in the autumn. “We will be seeking a meeting with the Department of Health so that we can make sure we are all clear as to what action needs to be taken and when it needs to be taken to further minimise the risk,” he told IMT.

According to correspondence from IBTS Chairperson Maura McGrath to Minister Harney, sent in March, the recent case of the haemophilia patient in the UK who was discovered to have vCJD, at autopsy, confirms that this issue needs to be dealt with ‘at the highest

level' to ensure that appropriate measures are taken to prevent onward transmission from transfusion and from other sources such as surgical instruments and endoscopes.

The Irish Government will obviously be keeping a close eye on developments in both the UK and France. But if either country fully adopts filtration and testing, will Ireland be forced to follow suit? "If we were seen to lag on this then the pressure on the Government would become unbearable," predicted Dr Murphy.

*See part two next week for options open to Ireland.*

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