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Department fixed despite new expert advice on vCJD

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*With the UK set to filter all blood destined for young children, **Dara Gantly** examines why the Irish Department of Health is not following suit*

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

Hawkins House has decided not to follow the independent expert advice of the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in the UK, which has advised the Department of Health in Britain to start filtering blood for children.

SaBTO is satisfied that there is now 'sufficient evidence' that this prion reduction filter reduces infectivity. The Committee has advised the UK government that filtered red cells be provided to those born since 1 January 1996, subject to satisfactory completion of the PRISM clinical trial due early next year.

"The committee also noted that, if implemented, the continuing requirement for prion filtration should be reviewed in the event that either further data on prevalence or efficacy of the filters becomes available," it added.

As revealed in *Irish Medical Times* earlier this year (August 21, 2009), Chief Medical Officer Dr Tony Holohan said the Department had not at the time 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.

This was despite the Irish Blood Transfusion Service (IBTS) informing Hawkins House earlier this year that "robust decision making on the part of the Minister" was now required on the issue, along with the immediate reestablishment of the expert vCJD Advisory Committee, which has not met since January 2006.

HIQA assessment

The Department has refused to sanction the reestablishment of this Irish expert group, which was chaired by UCD's Prof Bill Hall. Instead, it indicated back in the summer that Dr Holohan was to ask the Health Information and Quality Authority (HIQA) to carry out an assessment of the new technology.

Despite the UK body's recent recommendation to filter all blood destined for 13-year-olds, Hawkins House pointed out that the UK Department of Health has commissioned a health impact assessment "in light of the many outstanding questions about this technology, particularly in relation to its use on blood destined for children".

"The Department of Health has requested that the Health Information and Quality Authority (HIQA) undertake a health technology assessment on the potential introduction of this technology in the future," Hawkins House reiterated this month.

HIQA, however, could not be drawn on whether it had already started this assessment. In a brief reply to IMT, a spokesperson said the Department had raised the issue with HIQA and that the Authority would be 'considering it'.

It is understood no contact has taken place between HIQA and the IBTS on the matter. The IBTS has already expressed its concern that applying formal evaluations to the cost of prion filtration, and the parallel technology of prion testing, is 'fraught with difficulty'. Indeed, most western countries do not apply quality-adjusted life years (QALYs) gained standards to decisions on blood safety technologies, reflecting the level of societal concern at transfusion-transmitted infections.

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 a risk remains, and although this is likely to be small, the Service believes it is important to maintain its 'highly proactive stance in relation to this disease'.

Since variant CJD was first reported in 1996, a total of 208 patients with this disease from 11 countries have been identified, including: 167 from the UK (or 1 per 350,000 population), 23 from France (1 per 3 million) and four from Ireland (1 per million). The incidence of vCJD in Ireland is thus second only to that of the UK, and in front of France and all other countries.

'Do nothing'

The IBTS submitted a detailed 'options appraisal paper' to the Department last April on the possible avenues open to the Minister for Health on the issue. These included: 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 became clearer. The cost of these options range from zero (doing nothing) up to E75 million over five years. Thus far, the Department has chosen the first, and cheapest, option.

Filtering is very expensive, and further costs are incurred in the manufacturing process, to a total of about E80 to E100 per unit processed, according to the IBTS.

Filtering all donations in Ireland could thus cost up to E15 million per full year of operation, while 'cleaning' the blood prior to use for younger patients only, including paediatric and obstetric patients, would cost approximately E3 million per year in Ireland, the IBTS has estimated.

The companies behind the prion filter being considered in the UK — ProMetic and MacoPharma — have put a figure of 'a pound per person' to treat all donated blood in England (population 51 million).

IBTS Medical and Scientific Director Dr Willie Murphy told IMT that the blood board would be reconsidering its position in light of the recent SaBTO recommendation, and acknowledged that its previous 'option appraisal paper' could be criticised for not taking a more forceful position either way.

"Our view would be that we should filter everything and test everything as the technology becomes available, and that the Government should pay for it," he stated, adding that the IBTS would be back in touch with the Department to articulate its position yet again in light of the SaBTO move.

"Universal prion filtration is the ideal, but we should certainly begin with children and work from there," added Dr Murphy.

Crumlin filtration

The use of the filter has already been examined as part of a safety

study in 20 patients from Cork, and a further hundred-plus units are being transfused in Cavan General, where the system is in routine use.

The IBTS had planned to start using it at Crumlin Hospital earlier in the autumn, in order to gain more experience in paediatrics. However, Dr Murphy said this was shelved, as it was deemed 'inappropriate' to begin such studies in children when there was no government commitment to implement the technology.

"I think we should now revisit that decision," stated Dr Murphy, in light of the latest move in the UK.

Testing blood for vCJD represents a considerably cheaper option than filtration (€3 million v €15 million per year) for some or all of the same result. Filtration, however, would not cause any distress to donors, and would not therefore raise difficulties in maintaining the blood supply.

Amorfix Life Sciences — one of the companies that has developed a new test — has already 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. The UK government has awarded a tender to the same company, and a delegation from the IBTS has been over to France to inspect the field trials.

RCPI prion testing

The blood service has received ethics approval for the RCPI to carry out anonymised testing on 10,000 donor samples using the vCJD test that is in development. It said it was 'good to go' with the testing as soon as these kits became available.

While Dr Murphy agreed that 10,000 samples did seem a lot, such a large number was needed to carry out a proper assessment and to compare with other populations, such as in France or North America. "You need big numbers for low incidence diseases," he explained.

While about one-third of long-term carriers of vCJD in Ireland will have been infected during residence in the UK, and will therefore be excluded from donating blood, the remaining two-thirds will be eligible to donate. The IBTS estimates that up to 1 in 100,000 donors could be infected, though it is quite possible that there are no infectious donors in the population, since only a minority of people donate blood.

The leading expert in the UK, Prof Azra Ghani of Imperial College London, has put the worst-case estimate of a transfusion transmitted case of vCJD between now and 2015 in Ireland at one. However, there is a significant degree of uncertainty around her or anyone else's prediction of the future number of cases, particularly as the majority of the population — 60 per cent who are genetically less sensitive to the infection — may have an incubation period of up to 60 years.

Super-spreaders

Ireland could, of course, experience what is termed 'super-spreaders' — infectious individuals who by chance are among the very prolific donors. The IBTS believes that with a window period of vCJD that stretched over 20 years, such a person could donate an infectious unit 80 times.

Dr Murphy told IMT that whatever decision was taken with regard to prion filtration and testing, it was vital to 'decide who is taking responsibility for that decision'.

In terms of the impact of the disease, Ireland is next in line after the UK, and cannot ignore what action is being taken across the Irish Sea. "They have taken this step, and we need to take that into

accounted," concluded Dr Murphy.

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