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Defence options against vCJD

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*In the second part of a major investigation, **Dara Gantly** examines the options available to detect and filter out variant Creutzfeldt Jakob disease from blood donations. Read [part 1 of this article](#), which was published last week*

The latest Annual Report (2007) from the Irish Blood Transfusion Service (IBTS) suggests an unambiguous stance on using the very latest tests to protect our blood supply. On page 2, just before the Chairperson's message, and in a font size of 36, is the following: "The issue of safety is of paramount importance and every advance in screening and testing techniques is utilised."

In light of the decision taken by the Department of Health to adopt neither prion testing nor prion filtration to safeguard against the risk of transmitting variant Creutzfeldt Jakob disease (vCJD) from blood transfusion, it is questionable whether the same bold statement will appear in the IBTS's next report.

As exclusively revealed last week, Irish Medical Times has learned 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.

This is despite the IBTS informing Hawkins House earlier this year that 'robust decision-making on the part of the Minister' was now required, along with the immediate re-establishment of the expert CJD Advisory Committee, which has not met since January 2006.

While the danger to the blood supply from vCJD is estimated to be extremely low, the IBTS has told the Department that an infectious donor in the platelet apheresis panel could be 'catastrophic' if leucoreduction — the removal of white blood cells from a blood component — had not worked as a safety measure. While the IBTS indicated that this was extremely unlikely, it would be an 'intolerable risk' if a feasible test was developed.

This risk, however small, means it is prudent to continue to develop policy on the basis that there may be one or more infectious donors in the Irish population, the IBTS has stated. "We may be optimistic that the measures put in place to date and the natural history of the disease have resulted [in] very few transmissions in the last few years and in the future, but we cannot be certain."

The primary oral epidemic may be dying out in the UK, but the IBTS believes there are reasons to be guarded about the future. In particular, all confirmed cases to date have been in a subset of the population that is particularly sensitive to the infection and which makes up 40 per cent of the general population in Ireland and the UK. They are characterised by having a particular polymorphism at codon 129 of the PrP gene resulting in methionine/methionine (MM or Met/Met) expression at this locus. The remaining population express either valine/valine (VV; Val/Val) or methionine/valine (Mv; Met/Val).

Spongiform encephalopathy

This remaining 60 per cent are not immune. "It is known from previous epidemics of very similar diseases in humans — kuru and iatrogenic CJD — that cases of transmissible spongiform encephalopathy in this subset of the population arises less frequently and with a longer incubation period, which may be up to 60 years long. It is very likely that cases will arise in the less susceptible part of the population in time. It is reasonable to assume that such individuals will be infectious throughout the incubation period. This may not be true, but it cannot be excluded in the present state of knowledge," the IBTS stated in its report to Hawkins House.

So what are the options available to the Government, and what are their likely costs? The IBTS submitted a comprehensive 'options appraisal paper' to the Department in April detailing six possible avenues open to the Minister for Health. *IMT* has obtained a copy of this report through the Freedom of Information Act.

The first, and cheapest, option on the table is to 'do nothing' and maintain a 'watching brief' — the line the Department has chosen to take for the time being. The IBTS admits that it is quite possible no transmissions of vCJD from blood transfusion will happen. However, it is quite likely that some MV or VV individuals in the Irish population are infected with vCJD. "Indeed, it would be surprising if there were none," the report suggested.

One in 100,000 could be infected

While about one-third of long-term carriers 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. "We estimate that up to one 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 report suggests it is possible that the leucoreduction already in place removes infectivity from red cell units and platelet units donated by these donors, but this is 'unduly optimistic' at this time and cannot be considered to be a reliable position.

Of course, the cost of 'doing nothing' is, essentially, nothing. Yet the IBTS has warned the Department that should transmission occur, the Service would be exposed to litigation and would almost certainly be considered liable.

"While negligence would not be an issue provided certain steps were taken (such as explicit information to the public, appropriate debate in the Oireachtas and decision-making at Ministerial level), liability under consumer protection legislation would almost certainly be upheld."

Test all donations

Option number two is to test all donations, the cost of which is estimated at approximately €3 million a year. It is not clear if this

would prevent any infectious donations entering the transfusion chain, the report stated, since there is no possibility of doing definitive research based on real human cases. "It is also entirely possible that we would never know whether it was effective or not."

The IBTS said it was reasonable to assume that testing would identify some and perhaps all infectious donors, although this may include infected but non-infectious donors, where infectious agents are reduced by leucoreduction to a level that does not transmit infection to a recipient.

Several donors — estimated at present at around 100 per year, but this could be higher — would test positive due to false positive reactions. "Most of these cases will ultimately be resolved by further assays, but some morbidity will ensue in healthy people from the anxiety caused," the report acknowledged. There will also be a loss of donors who will not be willing to undergo the test given the uncertainties around the results and the possible consequences of a positive test, such as anxiety, and concerns about insurance and healthcare.

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

A filter has been developed that may remove infectious prions from red cell units, but not from platelets or plasma. Independent efficacy studies to test the manufacturer's claims are being conducted by the Health Protection Agency in the UK, a project in which the IBTS is a partner, but the data are not yet complete. The Service has performed safety studies on this filter in transfusion patients in Cork and Cavan, and is now ready to extend it into more general use — including at Our Lady's Children's Hospital, Crumlin.

The main drawback is that the filter removes about 20 per cent of the contents of the unit of blood, so that in general use many patients will need additional transfused units to meet their clinical requirement. The IBTS believes this is unlikely to be a critical issue as dosing of blood transfusions for individual patients is fairly crude, and a 20 per cent variation is unlikely to be of serious consequences in most cases.

Prion filtering

Filtering is expensive, and further costs are incurred in the manufacturing process, to a total of about €80 to €100 per unit processed. Filtering all donations in Ireland would cost up to €15 million per year of operation. However, it is understood another filter is emerging that would be significantly cheaper to adopt. A fourth option open to the Government is to use prion filtering for younger patients only, including paediatric and obstetric patients, which would cost approximately €3 million per year.

All filtration of blood for those over 70 would be unnecessary, and could not give any real value for money in terms of healthcare procured. For over-60s, the same is likely to be true, but there will be many possible exceptions. A person having a hip replacement at 60 has a life expectancy of 15-20 years on average, so that clinical disease may arise should transmission occur.

Filtering only for younger recipients maximises any return in healthcare gained for prion filtration. In practice, it should be possible to segregate most transfusions going to paediatric and

neonatal patients and to obstetric cases. However, the IBTS report said there were likely to be some instances where non-filtered blood would go to younger recipients, especially in hospitals with a mix of general and obstetric and/or paediatric practice. “While extensive efforts would be made to prevent this, in reality it will inevitably happen to some extent without a much more sophisticated control system at hospital level than currently exists.”

Tested apheresis donors

A combination of filtration and testing for all or some donations is another option, albeit one with a price tag of between €3 million and €18 million per annum. At the lower end, all red cell transfusions intended for use in children, pregnant women and young adults would be prion-filtered red cells and all platelet transfusions intended for this group would be from tested apheresis donors.

Filtering of red-cell donations and testing of platelet donations would be an ‘effective approach’, the IBTS stated, as it would limit the possibilities of distress to donors, should that emerge from current research to be an issue that could also endanger the blood supply. However, this would not be possible to do for the next two years.

A final option would be to filter donations for children only in 2009, while the picture around testing becomes clearer. This, the IBTS said, would cost €1.125 million to €1.7 million from June onwards.

This leaves one important question: is it legitimate to apply standard health economic arguments to the safety of our blood supply?

This concludes next week with Part 3. [Read Part 1](#)

Posted in [Guests](#) on 28 August 2009

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