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The cost of safe blood

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*In the final part of a three-part investigation, **Dara Gantly** asks whether it is legitimate to apply standard health economic arguments to blood safety. Read [part 1](#) and [part 2](#) of this article.*

The Chief Medical Officer of the Department of Health, **Dr Tony Holohan**, is understood to be in discussion with the Health Information and Quality Authority (HIQA) over the introduction of prion testing and prion filtration to safeguard against the risk of transmitting variant Creutzfeldt Jakob disease (vCJD) from blood transfusion.

In a statement to Irish Medical Times, a spokesperson for the Department said the CMO will discuss with HIQA the question of an 'appropriate assessment with regard to the potential introduction of these technologies in the future'.

Such an assessment is likely to be in the form of a Health Technology Assessment (HTA), designed to inform decision-makers on safe and effective health policies that are patient-focused and achieve best value. They usually include the evaluation of social and ethical issues, quality-adjusted life years (QALYs) gained, quality of end-of-life and cost effectiveness.

The Irish Blood Transfusion Service (IBTS) has given the Department of Health a detailed 'options appraisal paper' on the possible avenues open to the Minister on the introduction of both prion filtration and prion testing for vCJD.

These include: doing nothing; testing all donations; filtering all donations; filtering blood for younger recipients only; 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 — expenditure the IBTS says it cannot meet within current resources.

But standard health economic arguments are not traditionally applied to blood banks. This, experts explain, reflects the societal cost of the AIDS and hepatitis transmissions in the 1980s and 1990s, and the high value that has subsequently been placed on blood safety.

Financial considerations

In a report sent to the Department of Health back in April, which has been obtained by Irish Medical Times under the Freedom of Information Act, many of these financial considerations have already been examined by the IBTS — work that HIQA is likely to replicate. However, in light of the 'special relationship' we have with blood products and their potential contamination, the IBTS believes applying formal evaluations to the cost of prion filtration and prion testing is 'fraught with difficulty'.

Formal estimates of the likely number of individuals in Ireland infected with vCJD have been conducted in the past: the likely maximum was initially estimated at approximately 15, where the

number of cases in the UK was likely to be under 500. These figures, however, need to be updated.

As of June 2008, a total of just 208 patients with this disease from 11 countries have been identified, including 167 from the UK (or one per 350,000 population) and four from Ireland (one per million). British estimates have been based mainly on the result of a population study of appendix specimens from 1996 to 1999, where the observed prevalence of the disease was 1:4000.

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.

Infectious donors

The IBTS believes the most likely number of infectious donors in Ireland is actually zero. If it is assumed as a worst case that one in 100,000 donors are infectious, i.e. that there is one infectious donor per year, then the IBTS has estimated that the cost of filtration for a year (€15 million) would prevent, on average, 1.6 infectious donations being transfused; so €9,375,000 would prevent one infectious donation.

Approximately 85 per cent of donations go to people aged over fifty, with a mean life expectancy of fewer than 10 years. The incubation period for 40 per cent of infected recipients (MM homozygotes) from leucodepleted unites is likely to be greater than nine years, longer than the mean life expectancy. Therefore, even in the worst-case scenario where an infectious donor donates 1.6 times per year on average every year, almost all recipients will live for a shorter time than the incubation period.

Using such statistics, the IBTS suggests that the cost per QALYs gained in this group is, based on current knowledge, in the order of tens of millions of euro. Younger patients receiving blood transfusions, however, may have a normal life-expectancy. In an extreme setting, all young recipients of an infectious transfusion, irrespective of PrP genotype, or sensitivity to vCJD, could live long enough to develop clinical disease.

According to the IBTS, if we assume that up to 50 years are gained per younger recipient per infection prevented, and assume the worst case of one infectious donor per year, and that 10 per cent of blood transfusions go to younger patients, then the cost per year gained for the money spent on filtering blood for younger recipients would be €4.8 million.

“This probably represents an extremely optimistic estimate of the return for the money spent; it is two orders of magnitude higher than the cost per QALY generally considered good value for healthcare money, but is comparable to the health economics of nucleic acid virus testing of blood donations,” explained the IBTS in its report to the Department.

“Moreover, many western countries do not apply QALY standards to decisions on blood safety technologies, reflecting the level of societal concern at transfusion-transmitted infections,” it added.

Such calculations were also given with a chilling proviso: that Ireland could 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.

Each donation could be transfused to more than one recipient (as red-cell concentrates, platelets or cryoprecipitate), so that, in a worst case, one donor could infect a significant number of recipients. A similar possibility arises for platelet apheresis donors, where one donor may donate triple donations six or more times per year.

Testing blood donations for vCJD poses numerous ethical issues. Many of these dilemmas were considered by Prof Albert Weale of the University of Essex, in a report in 2005 for the UK's Health Protection Agency Centre for Infections. Its findings have been discussed by the Board of the IBTS.

It mentions that in 2001, the UK's National Blood Service donor research department commissioned a study to look at how blood donors might respond to vCJD testing. Overall, donors were not very concerned and maintained a 'healthy scepticism' towards media scares, but displayed a range of different levels of knowledge.

The more information people were given about vCJD (e.g. genetic susceptibility), the less certain they became about wanting to know their test or infection status. However, if donors were not given the result and continued to give blood that was discarded, this would be both an 'assault' (in law) on blood donors as well as a massive waste of resources.

IBTS Medical and Scientific Director Dr Willie Murphy believes that while the issue of informing donors is not completely black or white, in practical terms there is no real way around this. "Unless the nation, as a whole, says, 'Look, that's the way we're going to have to go to maintain this life-saving therapy', and we tell donors, 'We're testing you but we're not going to tell you the result. We may in fact call you for years and never use your blood.' But this would be a very messy situation."

The precedents set by the introduction of HIV and hepatitis C testing indicate a need to plan for the introduction of vCJD testing 'as expeditiously as possible', the UK ethics report went on to state. While accepting a possible loss of donations and donors due to the introduction of testing, and an uncertainty over the implications of reactivity to vCJD tests for the health of donors, neither of these were considered a barrier to the introduction of such tests — a conclusion clear from legal advice following the introduction of tests for hep C.

However, the report noted that loss of blood supply as a result of the testing regime may reach levels where patient safety is more threatened by the lack of blood than improved by the removal of vCJD positive donations.

Earlier this year, the IBTS carried out its own patient survey of donor attitudes on vCJD. According to Dr Murphy, the main concern of Irish donors was actually insurance. "They thought they could live with the uncertainty, given the value of blood transfusion. But they could not live with the notion that they would roll up their sleeves and be penalised with higher insurance premiums."

Social insurance

While a state-backed social insurance scheme might be one option, Dr Murphy suggested that the Irish Insurance Federation could also undertake that blood donors — who would be the only people subjected to this test — would not be penalised or required to disclose the information.

He believes that blood products do have a 'special status', equating them to pharmaceuticals rather than healthcare interventions. "We might argue over the drug margins and go for cheaper generics, but we don't say to the pharmaceutical manufactures that we'll leave out that safety step, or drop that quality control, to take 10 cent off the price. We allow manufactures to pass on the costs that they incur,

without looking at a quality analysis of those.”

Dr Murphy added that if one did apply traditional health economics to testing for vCJD, it would not add up – but neither would viral testing for hepatitis B or HIV. “We only have four donors a year with HIV, if that; sometimes just two. But we spend millions to identify those. It is quite likely that the units that they donate will go to older people who will die before they develop anything associated with HIV, which takes seven years. But, if a new, better test for HIV becomes available, of course we spend the money to do it. As a nation, we would be appalled if we didn’t.”

While his recommendation would be to sanction the new technologies, Dr Murphy said he could understand if the Department decided this was not a wise use of available healthcare resources. “But I think that decision should be a public one — explained in a public forum where everyone knows what they have done and why they have done it.

“I don’t think it should be a decision made by the Department of Health in a back room... They have to be able to stand over it and make it in the full glare of public scrutiny,” Dr Murphy stressed. And if either the UK or France adopts the technologies first, the pressure on the Irish Government may become ‘unbearable’, he added.

In the words of IBTS Chairperson Maura McGrath, we are reaching a juncture where ‘robust decision-making on the part of the Minister’ is now required. So have we learned nothing from the hepatitis C scandal? If the past teaches us anything, it is that those who cannot learn from it are bound to repeat their mistakes.

Read [part 1](#) and [part 2](#) of this article.

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