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15th June 1987.

The Editor
The Lancet
7 Adam Street
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Dear Sir

TESTING BLOOD DONORS FOR NON A NON B HEPATITIS - IRRATIONAL, PERHAPS BUT INESCAPABLE

Several recent letters to the Lancet have pointed out weaknesses in the arguments which have been used to support the introduction of blood donor screening to reduce transfusion transmitted Non A Non B hepatitis using Alanine Amino Transferase (ALT) and hepatitis B core antibody (anti-HBc) - so called surrogate marker testing (1, 2, 3).

Those authors have suggested that the UK transfusion services should not start a donor screening programme until we in the UK have carried out prospective controlled studies to find out how many cases of post transfusion hepatitis would actually be prevented, pointing out correctly that no large study to answer this critical question has yet been presented.

We do not wish to challenge this scientific conclusion. It is agreed that the size of the benefit to be gained from surrogate testing cannot be accurately established without a prospective study. However we do argue that the time for this study has now passed. Starting now will give us an answer in 3 to 4 years and that is probably 3 to 4 years too late. The introduction of surrogate marker testing for Non A Non B is now virtually inescapable, for three reasons.

Firstly, in 1988, the new European legislation on strict product liability comes into force in the UK. One aspect of this makes it clear that if harm should come to the recipient of a therapeutic product, the producer will be held liable unless he can demonstrate that he used all known methods and information to avoid the risk. It seems clear that under these rules a patient who developed Non A Non B hepatitis

following a transfusion of blood or a blood product would have a claim against the supplier of the blood if it was shown to come from a donor who had not been tested for both ALT elevation and anti-HBc. Britain is a party to these agreements.

Secondly, although we all hope that pooled plasma fractions will soon be made safe by heating or other anti-viral treatment, these processes remain to be validated in large scale trials. Meantime, even if surrogate marker screening would only modestly reduce the level of infectivity in these products, many would argue that some improvement is better than none.

Thirdly, the UK transfusion services, although the major suppliers of blood and blood products in this country, cannot afford to ignore the wishes of consumers to be supplied with "Non A Non B tested" products, even if it is believed that the real benefit in safety which is offered to the patient is marginal. Commercial suppliers of plasma products will not be slow to point out that their products are made from tested plasma and must therefore be safer. Clinicians and patients can hardly be blamed for taking note of this message. And this argument may be applied equally to whole blood, red cells, platelets and plasma. What better marketing ploy for a private blood bank than to emphasise that its donors are tested to exclude hepatitis using the standards applied in the United States, Germany and France. The local NHS blood supplier will have trouble shrugging off accusations of providing a second class product.

It is also worth taking a second look at the assumption that surrogate marker testing is necessarily a 'bad buy' in comparison with the tests that are accepted as essential to prevent other transfusion transmitted infections. Table 1 shows a calculation to illustrate the cost of surrogate testing to prevent one case of cirrhosis due to transfusion transmitted Non A Non B hepatitis. This should be compared with the cost of HIV testing to prevent one case of transfusion transmitted AIDS. Alternatively, one could compare the costs of the present practice of routinely hepatitis B testing all repeat blood donors (in whom the prevalence of infection is predictably extremely low). Table 2 shows how these testing costs relate to the gains in recipient safety. These calculations suggest that, even if the underlying assumptions are varied quite widely, the cost of preventing morbidity by surrogate marker testing for NANB hepatitis may be no greater, and could be less than those which are accepted for established screening programmes.

Looking at these three factors - producer's liability, competition and value for money, we suggest that the decision which has to be made now is when rather than whether the UK

transfusion services follow the US and European lead in donor screening.

Yours faithfully

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