Our ref:imf/190198dc

19th January 1998

Professor Sir David Carter
Chief Medical Officer
The Scottish office
Department of Health
St Andrew's House
Edinburgh
EH1 3DG

Dear Sir David,

Re: New Variant CJD and the Risk Assessment

I am writing because of concerns over the potential outcome of this risk assessment. It is not clear to us (and that includes colleagues who attended one of the earlier meetings) what the overall remit of this risk assessment is. I understand that Dr Keel has tried to ascertain this but has not had a specific response. Is the risk assessment limited to considering the potential risks of infective, abnormal prions in blood or is it going to consider the impact of attempts to exclude prions from the blood supply in terms of our ability to deliver blood and blood products to patients in Scotland? Just as it is clearly imperative that the risk assessment takes an appropriate view of the potential risks of prion disease in blood transfusions, it is equally important that the proposals take into account the potential risk to patients of the inability of UK Transfusion Services to supply in the light of some possible proposals.

A number of risks of this nature are apparent to us, and I would like to comment on some of these, and point out some of the responses which SNBTS is making in respect of the CJD problem.

Donor exclusions

We understand that consideration is being given to excluding from blood donation those donors who have previously received transfusions of blood or blood products. Apart from the difficulties of determining whether an individual donor has indeed received transfusions of blood or blood products the impact on blood supply is potentially high. We are in the process of carrying out surveys of donors so that we can provide figures to you or to the risk assessment group in the near future. Estimates in England vary from 5 to 20% loss of donors and in France, where cellular recipients only have been excluded, I am told that the figure is 6 - 7%. A 7% loss of red cells would effectively postpone most routine surgery in Scotland for some time and would require a major change in transfusion policy by, in the main, surgeons and anaesthetists. Such a loss to the donor base could be restored, if at all, only after considerable effort in recruitment and publicity and would lead to increased expenditure in the donor programme. The logic in excluding only cellular recipients is also suspect given that we are uncertain as to the means of potential transmission by blood transfusions if at all. Certainly the UK Haemophilia Directors do not consider that plasma products can be assumed to be free from prions (*vide infra*).

Exclusion of red cell recipients would also, at a stroke, close down our anti-D collection programme since we collect solely from boosted donors at present. Although comments on the Internet suggest that we could obtain supplies from elsewhere my expert colleagues within the field tell me that there is a world shortage of anti-D and it would not be possible to simply replace the Scottish product without diverting supplies from elsewhere and at considerable financial cost.

Plasma safety

The issue of plasma products has obviously been exercising both yourself and us recently following the Haemophilia Directors statement prior to Christmas and the media releases since then. It is often said that there is little evidence available with which to make an assessment as to the safety or otherwise of plasma products. Whereas this is true in the case of new variant CJD there is a significant body of evidence with regard to the likelihood of exclusion of Scrapie agent from various plasma derived products by fractionation. I am unclear as to whether such evidence is being presented to the risk assessment but this could be made available readily through Dr Bob Perry at the Protein Fractionation Centre. This seems to be particularly important at a time when the Haemophilia Directors are demanding a speeding up of the transition to recombinant products; or, failing this, the purchasing or processing of products derived from US plasma. The cost/benefit of either policy is clearly a matter for the Scottish Office and the Department of Health. However, we in SNBTS are very concerned about the medical assumptions which lead to the preference of US plasma over UK plasma. US derived plasma has increased rates of HIV and hepatitis, and although testing, heat treatment etc. reduces the risk, risk cannot be eliminated. Also, it may be false to assume that the US will remain free of nvCJD given the prevalence of international travel and, I understand, common systems for preparing animal feeds.

Can prions be excluded by plasma fractionation? With regard to our own processes we are developing "scale-down" models which could then be used to test for exclusion or otherwise of Scrapie agent. These experiments however will need to take place in a category 3 environment within a specialised company and we are in negotiations with such companies and will be obtaining quotes for this work in the near future. It does appear unlikely that we could get any results within much less than six months, however. Furthermore experiments to confirm whether blood products prepared in this way are infective requires animal experiments which will take a minimum of 18 months.

Testing for nvCJD

A test for new variant CJD would obviously be of great benefit. We are in communication with Professor David Anstee at Bristol who has access to research quantities of the monoclonal antibody recently published by the Swiss group (owned by Prionics). It appears likely that this antibody would be made available to the UK Blood Services if pilot studies look as if it may be suitable for the development of a diagnostic test. There would however be a substantial royalty payment required in favour of Prionics.

Autologous blood transfusion

The Chairman of SEAC, Sir John Pattison, was quoted last autumn as stating that autologous transfusion should be explored. This of course we are doing but in order to fully develop an autologous strategy this will require substantial investment. Not only in the autologous collection programme but in the education of patients and their physicians and surgeons. My personal view is that we will not make a major impact with regard to autologous transfusion until we have a system that requires informed consent prior to transfusion which will enable

each patient (other than emergencies) to be involved in the debate over the advisability or not of blood products.

We in SNBTS consider that new variant CJD is possibly the most serious challenge ever to the blood services, and certainly the greatest since HIV. The potential for causing wide spread alarm and substantial erosion of the donor base from an over reaction are, in my view, at least as likely to lead to patient morbidity and mortality as is an over cautious approach that could exclude donors and products from the transfusion process. I do not underestimate the scale of the problem faced by those undertaking the risk assessment but would urge that these views of SNBTS are put to them with all urgency. It seems vital to overall public health that the result of a narrow risk assessment exercise, which looks only at the risk of infective and abnormal prions in blood, is not published without the risks to patients of a lack of blood being similarly understood.

With kind regards

Yours sincerely

GRO-C

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