

3rd November 1995

Our ref: LMW/cmh
Your ref: SFMG/pmf

Dr S F M Grimmer
Chairman
East Suffolk Local Research Ethics Committee
The Ipswich Hospital NHS Trust
Heath Road
Ipswich
Suffolk IP4 5PD

Dear Dr Grimmer

Clinical Investigation of the Significance of Anti-HBc Positivity in Blood Donors

Thank you for your letter of 31st October letting me know of the Committee's concerns. In reply:

- 1) The lifestyle study questionnaire was primarily designed for routine donor counselling, which we regularly undertake in the National Blood Service. As far as donors are concerned we feel it is important to try and establish risk factors for infective markers in donors so that we can keep our selection criteria up-to-date. Such an assessment of donors also acts as an audit of the effectiveness of our donor selection procedures. However, I do take your point about using such a questionnaire on patients who have received transfusions. It should be remembered that we anticipate that very few patients in the study will in fact test positive for any markers of hepatitis B. Such patients will require appropriate counselling as to their own infectivity and implications for their future health. The questions regarding other risk factors could be discussed as part of the counselling interview, without the need to use a formal questionnaire. However, it would be important to know if patients readily admit to other risk factors such as intravenous drug use or homosexual contact. The problem is that if we do not actively try to elicit such other risk factors, we could falsely attribute a transmission to a blood components and thus falsely bias the results and conclusions of the study.

In summary, therefore, I think selective questioning of the few patients who test hepatitis B positive will be necessary to draw any valid conclusions from the study and for their own future health. It was never the intention to go through the questionnaire on the majority of patients who will test hepatitis B negative.

Dr S F M Grimmer

-2-

3rd November 1995

2. Your comments regarding life assurance are well taken. Again, this would only apply to donors or recipients who have markers of on-going hepatitis B infection. We anticipate that this will be rare, and that any individuals who have markers of hepatitis B will most likely have had an acute episode from which they will have made a full recovery with no long-term sequelae. I am not aware that a past history of hepatitis without such sequelae constitutes a weighting for life insurance. This can be discussed with the few recipients in whom ongoing hepatitis B is present.

I hope my comments will now allow you to approve this study. I look forward to hearing from you.

Yours sincerely

Dictated(by Dr Williamson and signed in her absence.)

Dr Lorna Williamson
Acting Director
University Lecturer in Transfusion Medicine

Copy to: JPA