

HHG/LJ

7th October 1993

SAME LETTER TO: All RTDs/Chief Executives - England and Wales

Dear

ANTI-HBc TESTING OF BLOOD DONATIONS

The DH Advisory Committee on the Microbiological Safety of Blood and Tissues from Transplantation (MSBT) which has replaced the ACVSB considered the above topic in detail at a meeting held on Monday 4th October 1993.

It was decided that the routine testing of all blood donations could not be justified at the present time.

This decision was reached after consideration of the following:

- (i) All ELISA tests for anti-HBc gave false positive results; even the more specific tests the false positivity rate appeared to be in the order of 10-fold.
- (ii) There were no agreed, satisfactory confirmatory tests which means that there will be an inability to provide definitive health information to a considerable number of donors.
- (iii) The provision of standards, particularly a GO/NO GO standard for anti-HBs will be a major problem.
- (iv) It is difficult to estimate the number of instances of transmission of HBV which will be prevented with the introduction of anti-HBc screening. It has been suggested that the maximum will be in the order of 100 per year but could be as low as 10. Also, the morbidity is ill-defined since many instances may be sub-clinical.
- (v) Approximately £3M per year will have to be added to the cost of blood products from the RTCs since central funding will not be available.

(vi) There was concern about the withdrawal of plasma containing anti-HBc and/or anti-HBs from the pools for fractionated products. Anti-HBc is not a mandatory test in the EEC for plasma destined to produce such products.

(vii) Anti-HBc testing is not widespread in Europe.

Needless to say, the decision was not taken lightly but was unanimous. I have discussed the matter with John Adey and we agree that this advice should be accepted and uniformly implemented. The use of anti-HBc tests as supplementary to HBsAg positives is not affected by this decision.

MSBT will keep the question of anti-HBc testing under review.

With kind regards.

Yours sincerely,

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Medical Director

c.c. Mr. J.F. Adey
Dr. A. Rejman
Prof. J.D. Cash

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