MEMORANDUM

VHC 1691

TO:

FROM: Dr H L Lloyd

SUBJECT: Hepatitis C Testing

DATE: 18 June 1991

At the recent Directors meeting held in York, Dr Gunson informed Transfusion Centre Directors that the start date for Hepatitis C Testing in the BTS would be 1st September 1991. He said that it would not be possible to put off testing any longer than this and suggested that this was due to a number of pressures, about which he was not very specific. From a number of things he said, it sounded as though the fact that a lot of European countries were now testing, made it imperative that we should start testing in the UK.

The fact that the September start date has been finalised before the various Second Generation trials have been completed, supports our original view that the trials of the Second Generation kits were being used merely as a smoke screen for the fact that some Transfusion Centres were unwilling or unable for other reasons to start the testing on the original date of 1st July 1991.

At the meeting I saw some data on the performance of the Second Generation kits and this all supports the view that the Second Generation test is not only satisfactory and performs as well as the first generation test, but also is significantly better, particularly in reducing the window period between infection and the point at which the antibody test becomes positive.

The Second Generation test includes structural and non-structural regions as well as a core epitope. The first generation test included only one non-structural region.

There was still considerable debate about the flow chart for confirmatory testing. It has been suggested that a further 2 month trial will take place in September and October 1991 which will enable the Virologists to decide on the exact nature of the confirmatory test flow chart. This appears to be aimed at reducing the number of samples that need to be referred to reference Centres for RIBA2. There was also discussion about the value of PCR. Basically PCR shows the presence of viral RNA and is believed to indicate infectivity. Anybody who is antibody positive both by original testing and by RIBA2 but is found to be PCR negative would be assumed to have effective antibodies but no circulating virus. These people if they exist would be suitable as donors and presumably their plasma would make a valuable contribution to plasma pools for immunoglobulin production.

Briefly the UBI kit was reviewed and although Sheffield have only done a very few samples through this system, it was noted that the three 15 minute incubations required, each to an accuracy of ± 1 minute, presented certain logistical problems. The repeat reactive rate at the moment appears to be much higher than by other tests. I understand that Leeds with the Ortho test have a repeat reactive rate of 0.86%. Liverpool have only just started testing by Ortho and therefore were not able to give their rate. I think that the Glasgow rate is marginally higher than ours at about 0.45%.

At the end of this meeting I felt confident that as a Centre we had made the right decision to proceed with Hepatitis C testing when we did. My only regret is that we didn't introduce it earlier. The coordinating activity of the National Directorate appears to have provided us with a lowest common denominator approach rather than a best possible approach.

GRO-C

GRO-C:Lloyd

15/6/91

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