POLICY-IN-CONFIDENCE

D R A F T

From: J Canavan EHF1A

Date: 30 November 1990

cc: Mr M Malone-Lee D Ops
Dr J S Metters DCMO
Mr J C Dobson EHF1
Mr A S Rejman MEDISD
Mr Merrett FA2B
Mr R Anderson EAO

HEPATITIS C ANTIBODY SCREENING TEST:

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD (ACVSB)

1 My submission of 7 August notified you of the intention to commence a pilot study to evaluate the two available screening tests (Ortho and Abbott) for the hepatitis C virus (HCV), following the advice of the ACVSB at its July meeting that the UK should introduce routine HCV screening of plasma and whole blood once the results of the pilot study were known.

2 The results of the pilot study have become available and this note sets out the case for and against the introduction of routine screening, the financial implications and the results of an economic appraisal, and seeks Minister's approval to commence screening in the NBTS. The other UK Health Ministers are also being asked to approve the introduction of routine testing in their transfusion services.

Background

3 HCV is considered to be the main, though not the only, cause of Non A Non B hepatitis (NANBH), which has become the most common form of post transfusion hepatitis. The disease may run a symptomless course, but in some cases it can result in chronic liver damage which may ultimately be fatal.

4 Since the middle of 1989 an Initial Screening Test (ELISA test) has been marketed which can identify supposed carriers of HCV. However, there were problems with this ELISA test as it produced false positives and there was no means of confirming whether positive cases were infectious.

5 Routine testing for HCV antibodies in all donated blood has been introduced in America, Australia, Japan, France, Italy (testing on a voluntary basis), Belgium, Spain, Luxembourg, Finland, Norway, Sweden and Denmark.

ACVSB Recommendations

6 In view of the deficiencies of the screening tests the ACVSB did not recommend their use in principle until its meeting in July 1990. The ELISA test made by Ortho and Abbott had by then been licensed in their country of origin (USA) by the Food and Drug Administration and more scientific data about the tests had become available. Also by then a supplementary test, RIBA, had been developed to the point where it could be used routinely. It was thought that RIBA testing together with the confirmatory test PCR would provide a means of identifying which of the positive reactions to the screening test were infectious.

7 The ACVSB recommended that pilot trials should be carried out before routine screening was introduced. This trial would determine if either of the two ELISA tests were preferable for use on the UK donor population and would also provide experience in using the supplementary tests and confirmatory tests.

Results of Pilot Trial

8 The results of the trial were considered by the ACVSB on 21 November. The trial showed that both screening tests were satisfactory for routine use in the Regional Transfusion Centres. However the initial screening tests identified two populations of positive samples with a degree of overlap between them. Samples positive with both tests were only one half to one third of the total in the various pilot centres. This underlined the importance of having supplementary tests to help determine which were truly positive. The samples identified as positive by the supplementary tests showed a much greater degree of conformity in identifying the truly positive reactions.

9 The Committee recommended that routine screening should be introduced as soon as practicable with the choice of screening test left to the Regional Transfusion Centres. Samples which are repeatedly positive by the screening test would be referred for supplementary testing. The donors of samples found to be still positive would be deferred from giving blood and would be counselled on the need to consult a doctor for further advice and testing. On the basis of the pilot study results we would expect approximately 12,000 donations in England to be referred for

supplementary testing in the first year of which [ ] would be found positive.

Financial Implications of Screening

10 The screening of blood donations using the three tests, ELISA + the two supplementary tests RIBA and PCR, would cost an estimated £5.73 million in the first year (para 6 of the Economic Appraisal at annex). This figure includes the cost of the test, the extra staff at the Transfusion Centres, counselling and follow-up of donors and cost of replacement of lost donors. The cost of any treatment of positive donors would be in addition to this sum. This cannot be readily quantified since the form of treatment is still only in experimental use and may not come into routine use.

Value for Money

11 Paragraph 11 onwards of the Economic Appraisal at the annex considers the likely benefits of a screening programme. Given the poverty of information available on which to base an assessment the conclusion about benefits must be uncertain. However based on reasonable assumptions the appraisal concludes that some form of screening programme could be cost beneficial.

Funding

12 No special provision has been made for HCV testing in the HCHS budget. The cost to RTCs of £4-4 1/2 million would therefore have to be found from the general allocation. Since

RTCs will be moving away from direct funding by Regions from 1 April 1991, it is likely that the additional cost of screening will be reflected in higher handling charges to hospitals for blood supplies. The PHLS would carry out the supplementary tests and they too would have to find the cost from their general allocation. The cost to them is likely to be of the order of £1-1 1/2 million a year.

13 A measure which could reduce costs would be to screen on a selective basis. However there are no indicators which can distinguish those more likely to be HCV carriers. Restricting screening to new donors and active donors on an annual basis would not be appropriate since the routes of transmission of HCV are not fully understood and a negative result on one donation would not necessarily mean that all subsequent donations would also be negative.

14 An option would be to use the ELISA test on its own, but this would be unsatisfactory because of the high rate of false positives which would give rise to considerable costs for unnecessary treatment and counselling. An alternative would be for all positives identified by the ELISA test to be further tested with just the RIBA test, but this could lead to potential litigation by people incorrectly diagnosed as positive. However those members of ACVSB who carried out the supplementary testing during the pilot trial will be considering whether they can develop criteria for restricting the use of PCR.

Case for Screening

15 The main arguments in favour of screening are:

- it is a public health measure which would reduce the incidence of post transfusion hepatitis and the spread of HCV in the community at large;

- it reduces the risk of litigation from those who develop hepatitis or cirrhosis as the result of a transfusion when screening tests are available;

- any delay is likely to be shortlived as the EC is developing common licensing requirements for blood products. Other EC countries have introduced anti-HCV screening and it is likely to be a requirement that the source material for the blood products should be tested for HCV antibody

Case Against

16 - The screening tests are far from perfect and even when used in conjunction with supplementary tests it is not absolutely certain that positive cases are truly infectious. Even if they are a recipient of infected blood would not necessarily develop clinical symptoms.

- Counselling donors will present difficulties in view of the uncertainty whether the donor will ever develop ~~suffer~~ adverse effects. Nevertheless a positive finding is however likely to induce anxiety in the donor and perhaps compromise his or her insurability.

- It will also be difficult to counsel on sexual behaviour in view of the uncertainty over modes of transmission.

- The outlay on screening will add to the general pressures on HA funds. In practice it is likely to mean that the newly introduced handling charges for blood will be higher than they otherwise would be.

Timing of Introduction

17 If it were decided to introduce routine screening there are some operational matters that need to be finalised. The RTCs will need to consider how quickly they could recruit extra staff and obtain the necessary equipment to support the screening programme. The NBTS will also need to consider what counselling should be given to donors. There would also need to be discussions with PHLS about where within their network the supplementary testing should be carried out. The Transfusion Services in the UK would also wish to co-ordinate preparations to introduce screening at the same time. In practice it is unlikely that routine screening could be introduced before 1 April 1991.

Conclusions

18 In view of the ACVSB's recommendation that routine screening should be introduced as a public health measure, the possible risk of litigation and the fact that other countries are routinely testing blood donations for the virus antibodies, any

further delay in the introduction of HCV testing in the UK would be difficult to defend.

19 We therefore recommend the introduction of routine screening for HCV antibodies. We ask if PS(L) is content that screening should be introduced and that preparations should be made to introduce it as soon as practicable.

J CANAVAN
505 Eileen House
Ext GRO-C