NOTE OF 6TH MEETING OF THE ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD, HANNIBAL HOUSE, 24 APRIL 1990

EC Directive on Blood Products

A small group chaired by Dr Gunson had been considering 75/318. The UK draft had been taken into account in the preparation of the review draft which had now been sent back to the UK drafting group. The UK group had updated the UK Guidelines and 'Europeanised' them. These had been agreed by the policy side of DoH and were now on route to MCA and hence to EC. Dr Ruthven Mitchell and Dr Perry seemed to know about these and were content. I cannot remember having seen them.

Introduction of Combined HIVI and II Tests

As all Health Departments had approved the introduction of the combined tests the transfusion service had agreed to commence routine testing from 1 June 1990. After some discussion it was agreed that there would require to be a run up to 1 June to ensure that the centres had the necessary expertise and experience and to ensure that all blood donations issued on 1 June and thereafter from the transfusion centres would have been tested for HIVI and II. This meant that donations taken a few days earlier for release on 1 June would require to have been tested. It was noted that blood issued previously to hospitals but held in their refrigerators might not have been tested for HIVII but every effort would be made to minimise this and in any event the numbers would be small.

The question was then raised about the tonnes of plasma which had already been separated and was in store. In particular there was the matter of the very valuable hyper-immune serum some of which might not be fractionated for several months to come. It was agreed that the statement to be made would indicate that all blood (but not blood products) issued from transfusion centres on or after 1 June would have been tested. Also that all donations after that date would be tested - this would mean that gradually all the plasma going into the pool after this date would have been tested. The opinion was also expressed that the production procedures would be equally effective against HIVII as it was for HIVI - this was based on the similarity of the 2 infective agents and not yet on scientific tests.

HTLVI Screening

It was stated that the protocol referred to in the minutes of the previous meeting was now in existence and was to be sent to DoH.

Hepatitis C

A summary of the proceedings at the ORTHO symposium held in London on 8 February is given in ACVSB 6/2 attached. It was agreed by those who attended that this was a rather disappointing symposium. The main conclusions reached were -

(a) that there was a need for a confirmatory test,

(b) that the ORTHO test lacked specificity.

(c) that more information was required.

The general drift of the symposium was that it was too soon to introduce the test on a routine basis. Dr Mortimer, who was at the symposium, felt that a confirmatory test was just round the corner.

Abbott Symposium held in Chicago

Dr Ruthven Mitchell reported on this symposium. He also circulated a paper ACVSB 6/3 which he had obtained while at the conference. It was apparently intimated at the meeting that this paper headed 'Guidelines' would in effect become a directive as soon as the Hepatitis C test had been approved by the FDA. This 'directive' would be issued by the American Association of Blood Banks, the American Red Cross and the Council of Community Blood Centres. The FDA had not yet approved this Hepatitis C test. The test was currently being carried out routinely in Australia since March and also in France and certain other European countries.

It was apparently made clear at the Chicago meeting that the main threat was litigation; the question had been asked whether it would improve blood supplies and even more importantly what to do with the donors who were found to be positive. Some say that 30% will revert to normality in 6 months. The main problem is that a long list of donors will be built up but it will not be possible to give them any reliable indication of what the future holds for them. The likely interest of the lawyers was noted.

Reference was made to an article in the New England Journal of Medicine by Miriam Alter. It would appear that most cases of Hepatitis C do not arise from blood transfusion. In proven cases which are related to drugs etc there is a high correlation between the HCV antibody tests and Hepatitis C but it was considered to be quite different in the BTS. It was reported that the Americans will also do surrogate testing ALT, HBcAb - possibly a total of 9 tests.

The Chairman indicated that he was somewhat disappointed as he had hoped for more from the 2 symposia; in particular he had expected more science to help with decisions. It would seem that the studies had shown that of every 6 persons who were HCV positive only one would be infectious. A confirmatory test RIBA was becoming available as a research tool but it costs £20 per test and would not be suitable for routine use.

After a very long discussion it was agreed -

(a) that there was inadequate information to introduce full routine testing,

(b) there should be a confirmatory test suitable for use in routine laboratories,

(c) The FDA had not, so far, licence to test and it was felt it would be comforting if the country that devised the test licensed it for use in its own area,

(d) it was agreed that there was a need to investigate the donor panel to find out how many were positive, what advice was to be given to the donor etc.

It was agreed therefore to carry out a large pilot study involving 100,000 blood donors. A small sub-committee including Dr Ruthven Mitchell was set up to draw up the protocol for submission to the Department and SHHD for funding.

Date of next meeting

A further meeting was arranged for Tuesday 24 July 1990.