NATIONAL DIRECTORATE OF THE NBTS

U.K. ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED DISEASES

Minutes of the sixth meeting held at the North Western Regional Health Authority on Tuesday 8th January 1991.

PRESENT:	Dr. H.H. Gunson (in the Chair) Prof. J.D. Cash Dr. Marcela Contreras Dr. E.A. Follett Dr. J. Gillon Dr. R. Mitchell Dr. P.P. Mortimer Dr. W. Wagstaff

1. Apologies for absence - Dr. R.S. Tedder.

2. The minutes of the fifth meeting held on Friday 16th March 1990 were approved.

3. **Matters arising**

3.1 Dr. Mitchell reported that he had consulted Professor Phillips who had agreed that deferral of donors for 12 months after taking anti-malarial therapy when visiting or living in an endemic malarial area, or following an attack of malaria, was an adequate safety margin. It was agreed that donors with a history of malaria must be seronegative before donating red cells.

He also reported that currently available tests for malarial antibodies were unreliable and may result in false negatives.

Dr. Mitchell would continue to liaise with Professor Phillips with respect to the provision of a suitable test and Dr. Contreras would consult with the London School of Hygiene and Tropical Medicine.

Additionally, Dr. Contreras would report on the number of donors at the North London RTC who had been tested for antibodies by ELISA and the number found positive.

Dr. Mitchell agreed to modify his flow chart (Appendix I).

ACTION - Dr. Mitchell/Dr. Contreras

3.2 Dr. Contreras reported that the HTLV I study had commenced although the number tested as yet was small. However, 2 anti-HTLV I positive donors had been found on screening and both were of Afro-Caribbean ethnic origin. Further reports would be available as the study progressed.

Dr. Contreras agreed to write to Dr. Brian McClelland concerning the testing of sera from intravenous drug users.

In answer to a question, Dr. Contreras stated that samples for PCR would be collected from donors who were confirmed anti-HTLV I, according to the terms of the protocol. She seemed to remember that blood from donors found repeatedly reactive was being stored frozen in glycigel for PCR testing by Dr. Tedder. (Dr. Contreras has confirmed that this is correct and she has confirmed, also, that samples for PCR are being collected from all confirmed anti-HTLV I positives to be forwarded to the reference laboratories).

ACTION - Dr. Contreras

4. **Anti-HCV Testing of Blood Donations**

4.1 The flow-chart prepared by Dr. Mitchell was discussed in considerable detail. It was recognised that the definition of a positive result was crucial and that differentiation between reactive results which differed from the manufacturer's criteria for a positive result should be made.

Dr. Mitchell agreed to amend the flow chart which effectively summarises the decisions reached (Appendix II).

4.2 Repeatable HCV seropositive donors will:

(i) have an ALT test performed

(ii) be referred to a reference laboratory (serum and plasma)

4.3 At the reference laboratory confirmation of the original screen positive results at the RTC will be undertaken. New/improved tests will also be used as part of an evaluation process.

The RIBA test will be performed by reference laboratories and used as the standard test to confirm seropositivity.

The PCR test is the only one which will detect viral RNA; hence PCR tests should be performed on all RIBA positive sera.

RIBA positive PCR positive results would be reported to the RTC as anti-HCV positive with detection of viral RNA.

RIBA positive PCR negative will be reported as anti-HCV positive with no evidence of viral RNA and a request for a further sample at the next attendance

will be made. It was agreed that RTCs would make every effort to ensure that the donor was retested no later than six months after the previous test.

4.4 When the ALT on the donor sample is ≥90 u/litre the donor will be recalled for counselling and a repeat test. If ALT tests on the repeat sample are:

(i) still ≥90 u/litre - the reasons for the raised ALT should be investigated and the donor should be referred to a liver specialist.

(ii) <90 u/litre - action need not be taken immediately if the donor is not confirmed HCV seropositive, but the records should be flagged for retesting for ALT on the next donation. Again efforts should be made to ensure that these tests were repeated no later than six months after the previous test.

4.5 When a donation is reported RIBA positive, PCR positive arrangements should be made for the donor to be counselled. This may be performed by trained medical or nursing staff at the RTC or by experienced hospital staff. When the latter course of action is to be followed, secure arrangements must be made with the donor's permission, usually through the patient's general practitioner.

RIBA positive, PCR positive donors who are counselled at RTCs should be referred for specialist advice.

4.6 Dr. J. Gillon had prepared a paper for the SNBTS on counselling of donors. This paper was discussed and comments were made. Dr. Contreras tabled a paper prepared for N. London RTC and agreed to write to Dr. Gillon with her comments. Dr. Gillon agreed to amend his paper following written comments from members of the Committee.

4.7 It was agreed that information should be provided for donors prior to the commencement of routine screening. This could be in the form of a leaflet.

4.8 The problem of the fate of plasma from donations which were anti-HCV unconfirmed repeatable positives was not resolved. It was agreed that the policies adopted in other countries, (Europe, Canada, Australia) should be sought on this matter.

4.9 Dr. Gunson reported that Miss. V.I. Rawlinson has agreed to monitor anti-HCV tests and Dr. Lee (Director, N. Western RTC) considered that financing could be made available for this work. Miss. Rawlinson needed advice

on how to programme the computer and it was suggested that Mrs. Janet Mortimer could be approached to assist in this matter.

4.10 The return of repeatably positive unconfirmed HCV seropositive donors to the active panel of donors was not resolved.

4.11 It was agreed that there may be an ethical obligation to inform patients who may have received transfusions in the past from anti-HCV positive donations. This will involve considerable additional work including testing of library samples and will have to be funded. Extension of this to epidemiological investigations should be the subject of separate research studies.

5. **Any other Business**

5.1 Dr. Barbara wrote to suggest that it would be useful to formalise the rules for testing for syphilis, anti-HIV and HBsAg.

Dr. Contreras proposed that a Committee of the UK NBTS and Reference Centres should be convened and chaired by Dr. J.A.J. Barbara.

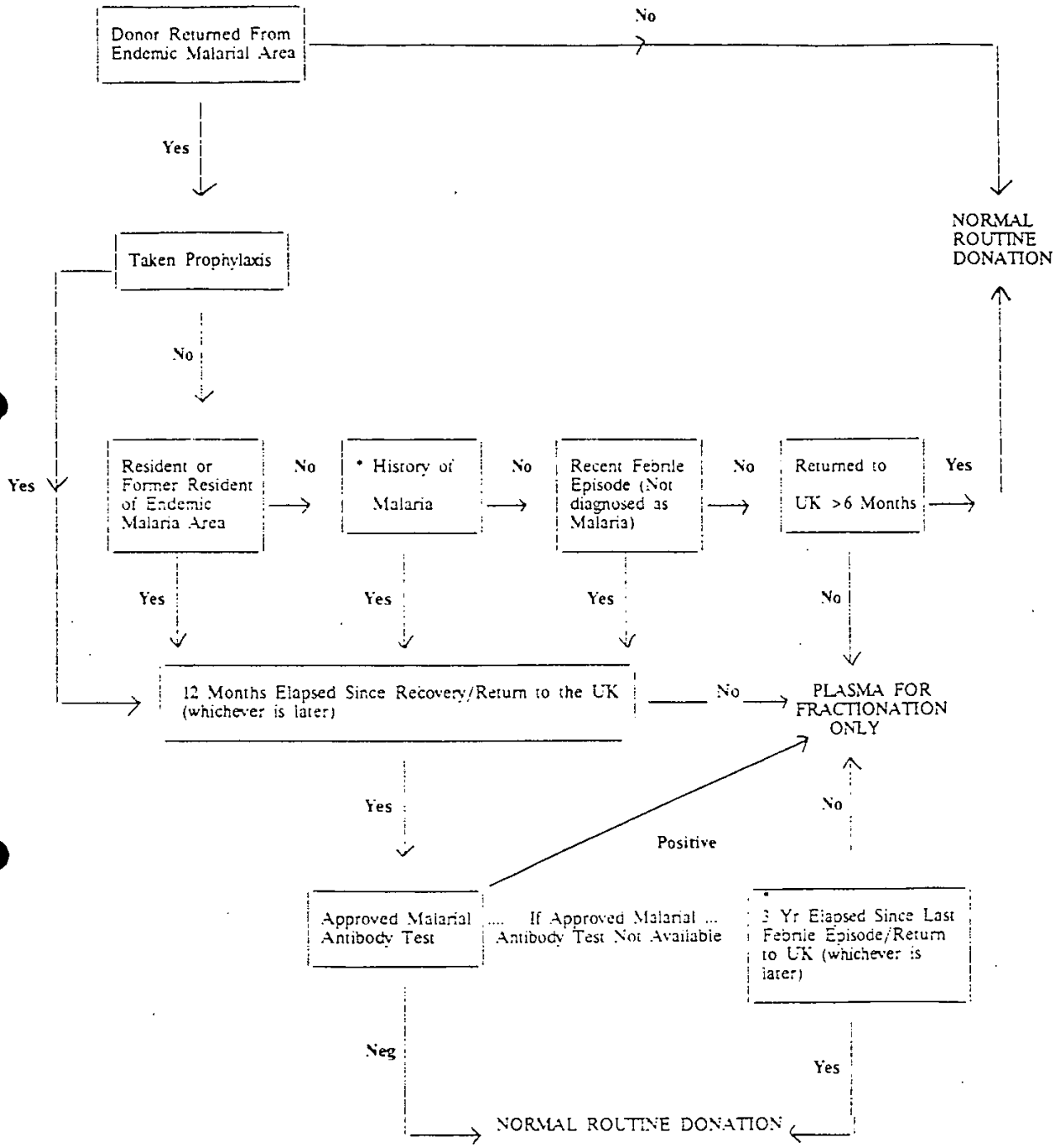
It was agreed to consider this proposal at the next meeting when members will have had time to consider this matter.

6. Date, time of next meeting

The next meeting will take place on Monday 25th March 1991 at 11.00 a.m. at the National Directorate, Manchester.

ELIGIBILITY FOR DONATION AFTER RETURN FROM MALARIAL AREAS

APPENDIX I
0902



* Donor with history of malaria must be sero negative before cellular donation can be used routinely.

APPENDIX II

0003

ACTION CHART
ANTI-HCV TESTING

INITIAL SCREENING TEST (Serum) ----------> NEGATIVE ----------> RELEASE BLOOD PRODUCTS

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* POSITIVE REACTION
(Retain Products in Quarantine)

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REPEAT SCREEN TESTS
(Serum x 2)

↓ ----------> ALL REPEAT TESTS NEGATIVE ----------> RELEASE BLOOD PRODUCTS

POSITIVE (Any Repeat Test)
Flag Donor Record (Label Blood and Blood Products 'BIOHAZARD' - NOT FOR TRANSFUSION)

↓

SCREEN TEST PLASMA FROM DONATION

(If plasma is only clear cut negative result obtained, investigations must be undertaken according to in-house SOP to identify and explain the apparent discrepancy.)

↓

POSITIVE

↓

ALT ESTIMATION
Perform ALT Estimation on original sample

↓

REFERENCE LABORATORY
(Serum and Plasma)

↓ POSITIVE

FLAG DONOR RECORD
(Recorded as Permanent Deferral Risk-Not to be Bled for Clinical Use. Arrange Counselling and Investigation of Donor.)

↓ NEGATIVE OR INDETERMINATE

If ALT > 90iu/litre arrange 1st visit. If < 90iu/litre wait 6 Months or Until Return Visit.

Subsequent Donations Tested as per Repeat Screen Tests and Samples Forwarded to Reference Laboratory.
Procedure for readmittance of donors to the active panel when antibody tests have been repeatedly positive at RTC but negative/indeterminate at the Reference Laboratory - See Over).

DEFINITION: Biohazard: Blood and Products Labelled 'BIOHAZARD' Must be Isolated and not used for Transfusion. Products Must be Discarded or Stored in Microbiological Laboratory for Future Investigation.

* Positive reaction is any test which meets manufacturers criteria or internal SOP where sensitivity is not less than manufacturers criteria.

D:AC-HCVT (6/2/91)