IN CONFIDENCE EAGA(5)6

EXPERT ADVISORY GROUP ON AIDS

SCREENING OF BLOOD DONATIONS FOR ANTI-HTLV III IN REGIONAL BLOOD TRANSFUSION CENTRES

REPORT FROM THE WORKING PARTY OF THE REGIONAL TRANSFUSION DIRECTORS' COMMITTEE

1) In accordance with the resolution of Expert Advisory Group on A.I.D.S. that Dr. A. Smithies consult with the National Blood Transfusion Service on matters relating to the screening of blood donations for anti-HTLV III, the Regional Transfusion Directors' Committee formed a Working Party comprising the following membership:

Dr. I.D. Fraser	- Director, South Western R.T.C. (Chairman)
Dr. K.Ll. Rogers	- Director, SE/SW Thames R.T.C.
Dr. L.A.D. Tovey	- Director, Yorkshire R.T.C.
Dr. A. Napier	- Director, Cardiff R.T.C.
Dr. M. Contreras	- Director, N.W. Thames R.T.C.
Dr. H.H. Gunson	- Director, North Western R.T.C.
Dr. D.B.L. McClelland	- Director, S.E. Scotland R.T.C.
(nominated by the S.N.B.T.S., Directors' Committee)	
Dr. A. Smithies	- D.H.S.S.

2) The contents of this document have been approved at full meetings of both the Regional Transfusion Directors' Committee and the S.N.B.T.S. Directors' Committee.

3) INTRODUCTION OF ANTI-HTLV III SCREENING TESTS

It was agreed that routine screening tests for anti-HTLV III should not be introduced until the following had taken place:

3.1 The proposed evaluation in the N.B.T.S. of different test kits has enabled satisfactory system(s) to be selected.

3.2 The establishment of Reference Centres for the purpose of carrying out nationally agreed confirmatory tests on sera giving positive results upon screening.

3.3 The establishment of alternative venues for anti-HTLV III tests on members of the General Public who are not blood donors.

It was further agreed that the introduction of anti-HTLV III testing in Regional Transfusion Centres should take place throughout the U.K. over the shortest period practicable following the agreed starting date.

4) DEFINITION OF ANTI-HTLV III TEST RESULTS AND ACTION TO BE TAKEN ON RECEIPT OF TEST RESULTS

The following scheme is proposed for the definition of test results and of the actions to be taken by the R.T.C. during the process of initial and confirmatory testing.

4.1 INITIAL SCREEN TEST NEGATIVE

Donation passed for use, providing all other tests are satisfactory.

4.2 INITIAL SCREEN TEST POSITIVE

Donation is labelled 'Biohazard' - NOT FOR TRANSFUSION

The screening test is repeated both on the initial sample and on a sample taken from the actual donation or integral donor line.

4.3 IF ONE OR BOTH REPEAT SCREENING TESTS POSITIVE

Sample of serum and plasma from donation sent to Reference Centre for confirmation.

Note: If the screening tests on the samples are POSITIVE and the test on the donation is NEGATIVE, the whole session or batch of tests must be rescreened from samples taken from the donations to exclude a sample transposition or labelling error.

4.4 IF BOTH REPEAT SCREENING TESTS NEGATIVE

The donor will remain on the panel and will not be informed. The donor will be recalled for a further donation. The donor records will be flagged so that particular attention will be given to the testing of a subsequent donation. (Sample may be sent to Reference Centre, depending on local agreements).

IF SCREENING TESTS ON SUBSEQUENT DONATION NEGATIVE

The donation will be made available for use. The flag will be removed from the donor's record.

IF SCREENING ON SUBSEQUENT DONATION POSITIVE

Donation discarded.
Sample of serum and plasma from donation sent to Reference Centre for confirmation.

4.5 CONFIRMATORY TESTS ON THE INITIAL DONATION POSITIVE

Suspend the donor from the panel.

Arrange to interview the donor (see 5.2 below). At the interview a SAMPLE OF BLOOD IS COLLECTED from the donor, and sent to the Reference Centre where the original confirmatory tests were carried out.

4.6 CONFIRMATORY TESTS ON THE INITIAL DONATION NEGATIVE

The donor's name will remain on the panel and the donor will not be informed. The donor will be recalled for at least one further regular donation. The donor's record will be flagged so that particular attention will be given to testing a further donation.

IF SCREENING TESTS ON SUBSEQUENT DONATION POSITIVE

The donation will be discarded.
A sample of serum and plasma from the donation will be sent to the Reference Laboratory for confirmatory tests.

IF CONFIRMATORY TESTS ON SUBSEQUENT DONATION NEGATIVE

This is probably a "non-specific result"
Remove name of the donor from the panel.
The donor should be interviewed and advised that his/her blood contains a factor which is not harmful, certainly not related to AIDS, but which interferes with routine testing of blood. The names of these donors may be transferred to a reserve panel for further samples to be taken at future dates for research purposes according to local arrangements.

IF CONFIRMATORY TESTS ON SUBSEQUENT DONATION POSITIVE

Proceed as in paragraph 4.5

IF SCREENING TESTS ON SUBSEQUENT DONATION NEGATIVE

Proceed as in paragraphs 4.1

5. PROCEDURES FOR THE HEALTH CARE OF DONORS

5.1 All donors will be notified before donating, by being sent or given a leaflet, that their donation will be tested for anti-HTLV III (Appendix I). Donors will be asked to confirm that they agree to the test being carried out (Appendix II).

Donations will not be accepted from donors who do not wish their blood to be tested.

5.2 On receipt of the first CONFIRMED positive result for anti-HTLV III the donor will be sent a letter by a member of the consultant staff at the Regional Transfusion Centre. A specimen letter is given in Appendix III. An early appointment will be arranged for the donor to be interviewed by a doctor from the Regional Transfusion Centre, who has been trained in counselling.

During this interview the significance of a positive anti-HTLV III result will be explained. The donor will be asked for the name and address of his Family Doctor and every effort will be made to ensure that the donor receives further medical consultation and that the results of the tests can be reported to his/her Family Doctor. A further sample of blood will be collected from the donor and sent to the Reference Centre where the original confirmatory tests were carried out.

6. CONFIDENTIALITY

Systems will be developed within the R.T.C.'s to ensure confidentiality of records. Staff within the R.T.C. will have information on a "need to know" basis. The main donor record (card or computer) will not have HTLV-III antibody positive data directly recorded on it, but will be identified by a reference such as "REFER TO LABORATORY FILE"

7. FOLLOW-UP OF RECIPIENTS OF PREVIOUS DONATIONS GIVEN BY DONORS FOUND TO BE HTLV-III POSITIVE

7.1 Efforts will be made to determine the names of any patients who received blood and components from the donations taken during the past five years and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient.

7.2 If plasma from any of the donations was sent for fractionation, full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible. Since patients suffering from haemophilia A and B are being investigated for anti-HTLV III at present, it is recommended that no additional follow-up be carried out.