APPENDIX I

ISSUE OF BLOOD AND BLOOD PRODUCTS WHICH HAVE NOT BEEN ANTI-HTLV III TESTED

At the present time all donations are tested for syphilis and hepatitis B. These tests have been performed for over 30 years and for 13 years respectively. Thus, a large number of regular donors have been tested on numerous occasions and positive results usually only occur in samples from new donors.

In order to avoid costly out of hours working, the practice employed in the Transfusion Service in this region is to test the incoming donations on the next available working day. This has proved to be satisfactory since by far the greatest quantity of our units of blood and products can be put into quarantine until the tests for disease transmission have been completed.

Up to the present, I have never been concerned with the requirement, which occurs occasionaly, to issue whole blood prior to the tests being carried out. Such issues are for patients who are seriously ill and the clinical condition can be said to over-ride the necessity for tests to be carried out. Responsibility for the use of this fresh untested blood has been undertaken without criticism by clinical consultants and has not caused any problems.

However, there is another product which is used to treat bleeding in patients, particularly those being treated for leukaemia, which is causing me concern. This product is platelet concentrates, which are prepared at the Transfusion Centres, has been subject to a considerable increase in use over the past few years and issues fluctuate widely depending on the number of patients being treated at any one time.

Whilst formerly the platelet concentrates were being used to treat haemorrhage in platelets, during the past two years they have been increasingly used to prevent haemorrhage in patients with platelet deficiency. Such transfusions are, therefore, planned, and one would expect to have fully tested platelet concentrates available. Because we were finding that the demand exceeded our ability to supply freely tested concentrates on every occasion, during 1984 in Manchester we took advantage of a new development in technology which allows their storage to be increased from three to five days. One year later, however, a further increase in demand has again meant that some of these planned transfusions are being performed without full testing.

I have not been too concerned on these occasions with respect to hepatitis B and syphilis since the platelet concentrates have been prepared from donations which have been tested previously. However, with respect to testing for anti-HTLV III a problem arises since we do not know the frequency of positives in this country as yet (in the U.S.A. it is 1 in 5000). Moreover, none of our donors have yet been tested and so for the first year of this testing they can be regarded as new donors.

I think that it is still justified in serious cases of haemorrhage to issue untested concentrates providing the clinical condition of the patient demands urgent treatment. With respect to the planned prophylactic transfusions, however, I am concerned that the clinical attendant might agree to use untested platelet concentrates against his/her better judgement. Should one platelet concentrate, during our routine tests carried out subsequently, be found to be positive for anti-HTLV III and the virus was transmitted to the patient, the R.H.A. may find itself suffering litigation, bearing in mind that the majority of these patients are immuno-suppressed and if they were to develop A.I.D.S., it appears to be a fatal disease.

I have had correspondence (which I attach to this Appendix) and a discussion with Mr. E.G. Jones, R.H.A. Legal Adviser, and have defined three courses of action as options:

(1) To ignore the anti-HTLV III testing of platelet concentrates for the purpose of issues and use donations, as at present, on the basis of previous tests for hepatitis B and syphilis.

Mr. Jones does not consider this to be a viable option for planned transfusions.

(2) To alter our general working arrangement to allow for testing of donations for disease transmission on the same day as collection.

This would be difficult to arrange logistically and would be expensive since it would have to be performed out of normal working hours.

(3) To make a 24-hour quarantine period obligatory unless it can be shown that the patient is bleeding so seriously that the use of untested platelet concentrates can be clinically justified.

At the Manchester R.T.C., all the facilities are available for this and it should be made easier when the Plasmapheresis Centre opens in October, 1985, since up to one half of the platelet concentrates used will be prepared using machines from a fully-tested panel of donors. Until that time it may be necessary to postpone some planned transfusions and also, if supplies become seriously depleted institute testing of donations on an emergency basis.

At Lancaster Centre where the pressures for issues of platelet concentrates is less than in Manchester the institution of 5-day platelet storage should enable the 24-hour quarantine period to be observed.

The Legal Adviser considers that Option 2 would be the safest for the R.H.A. and that the cost of one legal action could outstrip the cost of additional testing involved. However, the practicalities of putting this into action are very great, quite apart from the cost.

With regard to Option 3, the Legal Adviser considers that this would be acceptable if it were supported by a responsible body of medical opinion.

I should like to discuss these options with you so that an agreed policy can be defined.

My preference is for Option 3 for the following reasons:

(1) The establishment of the quarantine period is secure.

(2) The issue of untested concentrates would be a clinical decision based on the condition of the patient.

(3) The establishment of the Plasmapheresis Centre in Manchester should ease the current situation and until that Centre is functioning at maximum level, the right is retained to carry out emergency testing if supplies are short.

The disadvantage of this option is that some planned transfusions may have to be deferred for up to 24 hours and this may cause concern that haemorrhage may not be prevented. However, we will have to keep this to a minimum and keep this situation under close review.