NATIONAL DIRECTORATE OF THE NBTS

NBTS/CBLA LIAISON COMMITTEE

Minutes of the sixteenth meeting of the NBTS/CBLA Liaison Committee held on Wednesday 16th September 1992 at the NWRHA.

Present: Dr. H.H. Gunson (in the Chair)
Dr. C.C. Entwistle
Dr. R.S. Lane
Dr. D. Lee
Dr. M. McDougall
Dr. R.J. Moore
Mr. B.J. Savery
Mr. R. Walker

1. Apologies for absence were received from Dr. J.F. Harrison. The Chairman welcomed Dr. McDougall who was attending in her place.

2. The minutes of the last meeting held on 15th June were approved.

3. Matters arising:

3.1 **anti-HBs**

Dr. Lane reported that following discussion with PFC, Edinburgh, CBLA have identified 450-550 kg of hepatitis B hyperimmune plasma, unscreened for HCV which could be combined with a batch of Scottish plasma for fractionation into an i.v. anti-HBs immunoglobulin.

This material will have to be issued before the end of 1992. The time-scale will not allow for the preparation of a CTX and, therefore, the product will be available for sale as a "Special".

BPL could expect to receive 375,000-400,000 i.u. which will be sufficient to treat 5 or 6 patients.

Dr. Lane reported the results of a conversation with Dr. Roger Williams who considered that the efficacy of this treatment had been established. There were potentially between 30 and 40 patients per year which would benefit from this therapy and Dr. Williams confirmed that he had budgeted for immunoglobulin in the 1993/94 financial year.

The implication for future supply of anti-HBs specific plasma, if the above predictions were correct, was that the supply will have increased from 1000 kg to 6000 kg per year. It was recognised that such an increase would probably take up to three years and would also involve immunisation of volunteer donors.

It was agreed that Dr. Lee would take this matter to the Immunoglobulin Working Party who would recommend the number of donors required and develop a protocol for HBV immunisation. This information would be passed to Dr. Moore who would contact RTCs with regard to setting implementation targets over a three year period.

Action - Dr. Lee
Dr. Moore

3.2 **Anti-rabies Plasma**

Dr. Lane confirmed that 70 kg of source hyperimmune plasma would be sufficient for 1993/94.

Action - Dr. Moore

3.3 **Anti-varicella Zoster Plasma**

The EP requirement is for a potency of 100 iu/ml in the finished immunoglobulin. Currently the Ig being produced is <20 iu/ml. In order to meet the specification the plasma content of anti-VZ should be in the range 5-10 iu/ml.

The tests used show considerable variability and RTCs who are screening donations currently use different tests.

It was agreed:

(1) That the RTCs Yorkshire, N.W. Thames, Oxford and Wales, who provide approximately 80% of the anti-VZ plasma, will be requested to use the BPL test.

(2) The persons performing this test will be invited to BPL to see how the test is performed.

(3) BPL will provide

(i) a new standard for assessing hyperimmune sera

(ii) coded quality control sera for use on a monthly basis

Action - Dr. Gunson
Dr. Lane

3.4 **Anti-D immunoglobulin**

The survey carried out by the Chairman had revealed that only about 10% more plasma could be obtained by increasing the current rate of plasmapheresis of existing donors. However, at present this product is fractionated from small pools and this determines the

lower unit for anti-D potency. If BPL could scale this up to large pool fractionation it may be possible to lower the base limit. This may be a way in which more anti-D could be obtained without increasing the number of current donors.

BPL will produce a paper for the next meeting.

Action - Dr. Lane

Also, it was agreed that Dr. Lee, as co-ordinator of the ante-natal prophylaxis trial should contact the Royal College of Obstetricians to try and determine the likely policy with respect to the increase of ante-natal prophylaxis.

Action - Dr. Lee

3.5 **Anti-hepatitis A Plasma**

It was agreed that BPL would determine the base level of potency for anti-HA (i.e. 100 iu/ml or 50 iu/ml) with North London and then other RTCs who are contributing specific plasma can be informed and a protocol issued.

Action - Mr. Walker

3.6 Additional Item -

Strategic Reserve of anti-vaccinia Immunoglobulin

Dr. Lane reported that BPL could fractionate 100 kg plasma to produce such a strategic reserve. Methods for producing sufficient high titre plasma were discussed. However, the question arose with respect to the number of laboratories actively handling live smallpox virus and whether all were required. Also, enquiries should be made with reference to existing stocks of such immunoglobulin, e.g. Pasteur Institute, NIH.

The Chairman agreed to consult, initially, the Director of the PHLS, Manchester, who had made the request for this strategic reserve.

Action - Dr. Gunson

3.7 **Positive identification of packs at BPL**

(i) Dr. Lane reported that he had not had affirmative replies from all RTCs. **It was agreed** that this was essential and Dr. Lane would endeavour to elicit suitable responses.

Action - Dr. Lane

(ii) Dr. Gunson reported that the UKBTS Labels Working Party had recommended that Autopheresis C packs should be paired in the

same box when distributed to BPL. Dr. Snape had written to the Chairman agreeing to this solution as concessionary and made other suggestions with respect to documentation. Following clarification of some aspects of Dr. Snape's letter the Chairman will write to RTCs with a starting date no later than November 1992.

The Chairman pointed out that this was a difficult matter to resolve satisfactorily since, from the RTCs point of view, it was entirely logical to number these donations with the same number since they were from the same donor and were the same donation. It was evident that mutual difficulties had not been appreciated. Until CODABAR is replaced by an alpha-numeric code it will be difficult to identify such plasma donations as two different parts of the same donation. International discussions are taking place with respect to the introduction of Code 128 to replace CODABAR.

Action - Dr. Gunson

3.8 **Virally inactivated FFP**

Dr. Lane reported that two trials were proposed using:

(i) solvent-detergent treated plasma from Octapharma. The CTX was now ready for approval and the contract was being prepared. This plasma should be available by the end of 1992

(ii) pasteurised plasma from Lille. The Lille fractionators required a more comprehensive testing regimen than currently carried out in the U.K. Prof. Cash had written to Lille to seek clarification and it was understood that they would not relax their specifications. It had been agreed that samples would accompany the donations and Lille would perform the additional tests

Further information will follow.

4. **Plasma Supply**

4.1 The statistics for July 1992 were presented. Dr. Moore agreed to provide a cumulative graph for April to July.

Action - Dr. Moore

4.2 Dr. Lane said that he had received a letter from Dr. Williamson (Cambridge RTC) saying that they could

provide an extra 2 tonnes of plasma. Dr. Moore was aware of this correspondence which should have been directed to him since he co-ordinates the plasma supply. He recommended that this offer should be accepted since experience in previous years had shown that there was inevitably a shortfall at one or more RTC by the end of the year.

A suitable response would be given.

Action - Dr. Lane
Dr. Moore

5. **Plasma Specification**

5.1 The proposal that ELISA positive RIBA negative plasma was acceptable for fractionation could not be endorsed by BPL. Their criterion was that plasma should be fractionated only if the red cells are available for transfusion. The MCA had been consulted by DH and their response was awaited. BPL's policy could be revised in the light of changes in policy in RTCs following a further proposed study on the use of two ELISAs for screening donations.

5.2 **Parvovirus B19 antigen**

It was reported that SNBTS were proposing to screen plasma for this organism.

BPLs plans were not yet formulated and **it was agreed** that the implications for the NBTS of such screening would be discussed prior to its introduction.

Action - Mr. Walker

5.3 **Provision of donor pilot samples for BPL testing**

It was agreed that a trial would be undertaken in conjunction with Dr. Lee (North Western RTC) and initially these samples would be used for anti-VZ screening at BPL since with the increase in potency for this plasma there may be a shortfall. Dr. Lane will set out proposals for Dr. Lee to consider.

Action - Dr. Lane
Dr. Lee

6. **Production of Cryoprecipitate in RTCs**

6.1 In order to have some idea on the use of this product as a source of fibrinogen it would be interesting to have details of the annual issues of cyroprecipitate for this purpose.

Dr. Moore agreed to try and find out.

Action - Dr. Moore

6.2 In association with this it was understood the Northern RTC had been sending cryo-supernatant plasma to SNBTS for the preparation of fibrin glue. SNBTS would welcome further supplies.

Dr. Moore agreed that he would circulate RTCs and find out how much of this product was available and the level of financial compensation required.

Action - Dr. Moore

7. **German Federal Ministry of Health Study of Self-Sufficiency**

It was agreed that the data required need not contain any commercially confidential material.

8. **National Purchasing Unit**

It was noted that both the National Directorate and BPL were due to meet their representatives shortly.

9. Any other business

9.1 Dr. Moore asked if there was any data from BPL concerning the fractionation of plasma in regional pools since this may assist in determining optimum methods for plasma collection. Dr. Lane replied that several problems had been encountered during this procedure. He would prepare a paper for the next meeting.

Action - Dr. Lane

10. The next meeting will be held at CBLA on Thursday 10th December 1992 at 10.30 a.m.