

NATIONAL DIRECTORATE OF THE NBTS

NBTS/CBLA LIAISON COMMITTEE

The Fourth meeting of this Committee will be held on Thursday 10th August 1989 in the Crest, CBLA at 10.30 a.m.

A G E N D A

1. Apologies for absence
2. Minutes of the third meeting held on Wednesday 17th May 1989 - previously circulated
3. Matters arising:
 - 3.1 Prices for specific plasma *table paper.*
 - 3.2 CMV immunoglobulin
- report from Immunoglobulin Working Party LC9/89 *report from B. Lane. on demand supply of fluids*
 - 3.3 Guidelines for trials involving manufacturers equipment, NBTS and BPL *table paper.*

Amended paper by Mr. Crowley will be tabled following recommendations of NBTS Management Committee
 - 3.4 Progress of trial with Autopheresis C plasma ex platelets
4. Content of Factor VIII in vials
- 5.1 Cross-accounting - DH review meeting, 8th August 1989
- implications ^{for} of NBTS/CBLA liaison
- 5.2 Future of PHLS distribution mechanism *Letter John Clarke.*
6. Supply of blood and blood products in War
- potential stockpile of blood products at BPL LC10/89
7. Bar coding of source plasma and plasma products - to be tabled LC11/89
8. Any other business *Haemovetico letter*
9. Date, time and place of next meeting

Thurs 16th Nov.

NATIONAL DIRECTORATE OF THE NBTS

NBTS/CBLA Liaison Committee

Minutes of the 3rd meeting of the NBTS/CBLA Liaison Committee held at the Crest, Blood Products Laboratory on Wednesday 17th May, 1989 at 10.30 a.m.

Present: Dr. H.H. Gunson (Chairman)
Dr. F.A. Ala
Mr. B.J. Crowley
Dr. J.F. Harrison
Dr. R.S. Lane
Dr. R.J. Moore
Mr. B.J. Savery

1. Apologies for absence - Dr. M. Contreras
Dr. D. Lee
2. The minutes of the second meeting were accepted as a true record.
3. Matters Arising

3.1 Price For Specific Plasmas

The paper setting out proposals for a banded price structure for specific plasmas as discussed. It was agreed that anti-D plasma would be priced in three bands according to potency. Subject to detailed calculation, these bands would be:-

| | | |
|---------|------------|----------------|
| Band 1; | <100 i.u. | <i>and</i> £80 |
| Band 2; | 1-300 i.u. | £130 |
| Band 3; | >300 i.u. | £190 |

Banding would be according to the assay done by the dispatching RTC who would be expected to indicate the banding on the dispatch note. BPL will notify whether different bands need to be packed separately for transit. It was further agreed that the price for recovered anti-Tetanus plasma would be reduced to £50; the price for apheresed anti-Tetanus plasma would remain at £80. Increases in the price for anti-HbS plasma and anti-VZ plasma were discussed and it was agreed that whilst anti-VZ should remain at £80, some upward adjustment of anti-HbS might be possible within the overall planned costs. BPL will consider and notify the Directorate.

As a general point, it was agreed that further adjustment of these prices within the year was not desirable once these previously recognised anomalies were corrected.

The new prices would not be retrospective but would apply from 1st June 1989.

Action: B.J. Savery/R.J. Moore

3.2 Testing Plasma For ALT

Dr. Gunson explained that from the point of view of the NBTS and its responsibility towards the recipient, it was the general view that the introduction of ALT testing was unnecessary. However, it was recognised that CBLA requirements for the future sale of surplus products to other countries and the development of new products such as intra-venous immunoglobulins would require an ALT tested plasma. Mr. Crowley agreed that if the case for ALT testing rested on the benefit to CBLA, then it was up to them to produce a fully costed appraisal. It was agreed that a combined paper incorporating the benefit to CBLA and the costs to the NBTS of ALT testing would be prepared for the next meeting, by which time results from the 3 centre study and information on European practice would also be available.

Action: R.J. Moore/B.J. Savery

3.3 Audit of Manufacturing Procedures

Dr. Moore reported that courses for QA Managers in the BTS had been organised for the weeks commencing 13th and 27th of November. Each course would be the same and last one week, and would be run by David Begg Associates. Their intention was to provide a uniform training on quality management specially tuned to the BTS.

About 12 places would be available on each course, enabling one person to attend from each centre in the U.K. CBLA expressed a wish to send an attendee on the course.

Dr. Gunson explained that once everyone had been trained in the same way, audit teams drawn from QA Managers would be organised to give an external audit to each others RTC. CBLA would be involved in the team, and would be open to audit. Mr. Crowley welcomed this arrangement which would start early in 1990.

4. Issues Of CMV Immunoglobulin

The Immunoglobulin Working Party had raised the problem of distribution of CMV immunoglobulins. Dr. Lane explained that currently CMV immunoglobulin was ^{su}applied by three routes:-

- a) To clinical trials.
- b) To those RTC's who ask.
- c) On demand to other users.

NBTS representatives agreed that the product should only be supplied via RTC's. Dr. Lane agreed to provide details of demand and distribution to support a proposal for the basis of supply in the future.

In the meantime the present agreement whereby CBLA paid for the CMV plasma yet supplied CMV immunoglobulin free of charge would continue.

Action: R.S. Lane

5. Progress In Cross-Accounting

Mr. Savery reported that differences between Regions on whether or not product costs were passed on to District users was leading to confusion. Where costs were passed on to Districts, commercial suppliers were sometimes being considered as alternatives to BPL. Dr. Moore expressed the hope that following a meeting of Regional Treasurers representatives on 8th May, a common policy of Regions absorbing all costs and supplying 'free' product to districts would be adopted. In some cases however it was difficult for Regions to claw back from District budgets money previously allocated.

It was agreed that further close monitoring of the situation was essential.

5.2 Delivery Of Plasma And Products

Dr. Moore summarised reports from RTC's showing that albumin deliveries from BPL in April had been significantly below amounts ordered. Particularly deliveries of 4.5% 500ml were only 40% of monthly orders and no deliveries of 4.5% 50ml and 20% 50ml had been made. In some regions where 2 x 250mls had been substituted for 1 x 500mls the price charged had been the 250ml price rather than the 500ml; RTC's had complained about this practice.

Dr. Lane argued that RTC's had been notified in advance by the Commercial Department that albumin supplies in the first quarter would be restricted, RTC's should not therefore have been surprised when orders could not be fulfilled. When measured against amounts promised by the commercial department, deliveries were met in full. Further, 20% 50ml and 4.5% 50ml should not have been ordered since although they appear on the price list BPL do not make them.

Dr. Harrison and Dr. Ala said they had been unaware of any restrictions when ordering, the shortages would make great difficulties for the NBTS. Dr. Moore said RTC's had been encouraged as agreed at the last Liaison meeting to order one quarter of their estimates of all products except Factor VIII (cf Para 3.3.2 minutes of the 2nd NBTS/CBLA Liaison meeting). On this basis RTC's had attempted to persuade users to rely entirely on BPL albumin. Failure to deliver against order was losing BPL customers and straining credibility.

Mr. Crowley apologised for the mix-up over 50ml availability and said that he would monitor unfilled orders on a regular basis. However, albumin would remain in short supply during the next quarter. After discussion it was agreed that where 2 x 250ml bottles were substituted for 500ml due to supply difficulties then the price for 1 x 500ml would be charged.

Mr. Crowley said that Factor VIII would be available in larger quantities than anticipated. BPL would advise the Directorate so that RTC allocations could be increased.

It was agreed that Time Expired Plasma would not be paid for by BPL. Nevertheless RTC's would continue to send it to BPL who would endeavour to use it if possible.

6. Any Other Business

With regard to platelet poor plasma from the Autopheresis C machine, Dr. Gunson said that those RTC's taking part in the collection of a 300kg pool for process trials at BPL had failed to reach agreement with Dr. Lane over a fair price for the plasma.

After discussion over the costs which the manufacturer, CBLA and the NBTS could be expected to bear in such a trial, Mr. Crowley agreed to draft a policy paper which would suggest guidelines for this and future trials. It would be discussed by the Directorate at the next Management Committee meeting on the 1st June.

Action: B.J. Crowley

7. Date Of Next Meeting

The next meeting will be on Thursday 10th August, 1989.