Universal Leucodepletion Programme Implementation Board Meeting
Wednesday, 14 July 1999
Postgraduate Medical Centre, Queen Elizabeth Hospital

Present:

Alan Slopecki (AS)	Neil Beckman (NB)
Tim Wallington (TW)	Terry Male (TM) (from 11.30am)
Richard Bedford (RB)	Angela Robinson (AR) (until 11.30am)
Lorna Williamson (LW)	Steve Morgan (SM)
Peter Garwood (PG)	

100. **Apologies for Absence:** Nick Tandy (NT)

101. **Meeting Quorate / Declaration of Interests**

The meeting was declared quorate by the Chairman. Declaration of interests of those present is as previously minuted.

102. **Minutes of Last Meeting**

Item 98.5 - second bullet - to be amended to read Pall plant in Los Angeles. Third bullet - to be amended to read "Concern was also expressed at Pall's ability to scale-up."

Item 81(70)(70.1) (from Minutes of 12 May) - Bag Squeezing - to be amended again to read "the National Quality Group has agreed that a preferable option to bag squeezing is to bring packs into an ambient temperature environment."

These Minutes were then agreed as an accurate record. They could now be distributed to colleagues as Board Members felt to be fit.

103. **Matters Arising**

(94)(81) *Labels*

Take under item 105.

(94)(87.7) *Discard Information*

TW to progress report from Michele Ashford for the next meeting re the national figures for losses specifically due to LD processing. **(ACTION: TW).**

(98.4) *NEQAS*

The Ops Dirs are requested to send to LW the contact and Head of Quality names and addresses of each Centre to receive the results. LW will forward to NEQAS by mid-August. **(ACTION: Ops Dirs)**. TW had recently received a letter from the scheme organiser addressing the question of a steering committee, expressing their intention to request CPA Accreditation after the pilot and indicating that the first distribution would be in September. SM has approved invoice and this will be recharged to the Zones shortly. Currently the SLA is being drafted.

(98.7) *Increased collection against losses (NT)*

In the absence of NT this Agenda item was held over to the next meeting.

104. **Contingency to manage process failure**

RB presented the updated draft plans. Discussion and comments will be incorporated and updated plans will be presented at the August LD PIB. **(ACTION: RB)**. The discussion centred around the following points:

- Clarification of the move at Stage 3 to another site if the problem is not easily identifiable. The drafting of a second supplementary document, to consider 100% counting and relabelling as a last option was considered necessary.
- Clarification of the clinical significance of the upper trigger limit of 30. Section 5 needs reworking to establish the defining levels and their clinical justification. LW to supply wording to RB **(ACTION: LW)**.
- Clarification of the action taken when there is an occasional major failure as compared to a general trend towards the trigger limit.
- Testing the plans using real life scenarios to check how they work in practice. These are only Guidelines, no SOP will be issued. It was therefore felt necessary to provide training for the Medical Staff, possibly a one-day Workshop to clarify their use. **(ACTION: TW)**.

105. **FFP / Cryo implementation**

AR confirmed that the DoH had accepted that not all blood components issued after 1 Nov 99 would necessarily be Leucodepleted. However, specifically they had raised the issue of FFP. Currently there are no Clinical Guidelines for the Leucodepletion of FFP. RB confirmed that a better indication of stocks in the Hospitals would be available when replies are received back from the NAT letter. This issue will be revisited by the LD PIB in Sept 99, in the light of experience gained in the NAT project, to consider whether recall of frozen products post-millennium is appropriate. RB agreed to prepare a discussion paper for the Sept 99 LD PIB. **(ACTION: RB)**.

LW had received a reply from the Northern Ireland BTS who confirmed their procedures for this occurrence and requesting an approx. date for recall if needs be. LW would chase the Welsh and Scottish BTS's. **(ACTION: LW)**. Confirmation that the new labels are being prepared was needed. PG will ask Mike Clarke. **(ACTION: PG)**. RB agreed to communicate with the Hospitals when the new codes are available. **(ACTION: RB)**.

106. **Commissioning / validation of individual IMAGN machines**

Concern had been expressed about the reliability of the IMAGN machines in the light of NB's protocol being used in the L&SE and M&SW Zones. The 2 L&SE machines passed, the 2 M&SW ones failed. IMAGN have been contacted and technical problems due to the machine voltages have been blamed for the two failures. This has now been corrected. IMAGN responded well to the problems but a National contact was thought to be necessary. LW to nominate. **(ACTION: LW)**. In the light of these failures the Protocol will be taken back to the Sci/Qual Group for further discussion. **(ACTION: LW)**.

107. **Sickle Cell Trait**

RB reported that the operations group had been set up and progress was being made. However, this may take 6/8 weeks on the operational side. Similarly the Donor Care Working Group is active in dealing with this issue. There was discussion of the time scale for the implementation of procedres for the optimal handling of HbS donations. At around 50% red cell LD these donations are not having a discernable impact on product quality. Figures from L & SW suggest they make up less than 0.1% of donations. In the light of these observations and realising the complexity of certain of the issues that must be resolved the PIB agreed that implemnted policies for HbS are not on the critical path to universal LD. TW to discuss with Ops and Donor Care grps **(Action TW)** The issue will be revisited at the Sept 99 PIB.

108. **Reports / Reviews**

108.1 **Zonal Implementation Board, Northern Zone**

Report presented and filed with the Minutes.

The rewriting of the National SOP's into the OrCID format in order to make them useful throughout the Zone is more labour intensive than anticipated. After discussion is was felt necessary to allow Ed Harvey copies of draft SOP's to give as much time as possible for converting.

108.2 **Zonal Implementation Board, L&SE Zone**

Report presented and filed with the Minutes.

Building work is progressing well with contingency plans in place for any delays.

Currently 40% of Red Cells are being Leucodepleted which is encouraging and on schedule.

108.3 **Zonal Implementation Board, M&SW Zone**

Report presented and filed with the Minutes.

There have been significant improvements with the ongoing problems in the Zone with staffing levels.

Bristol has always been the high risk area in the Zone and still continues to be so.

A version of Quality Monitor Software should be available by the end of next week. NB to provide dates for roll-out to the Aug PIB. **(ACTION: NB)**.

Currently 50% of Red Cells are being Leucodepleted which is encouraging and on schedule.

108.4 **R&D Report**

Report presented and filed with the Minutes.

- The RZ2000 Baxter filter is looking good, using counting by all available techniques.
- The R3000 Baxter filter looks excellent and this filter has now been signed off at Phase 0.
- Janet Rider's work in Bristol has confirmed that BD reagents are giving lower counts in Coulter and BD machines. Tendering will commence shortly.
- LW has met with Dr Shield of the NIBSC and has clarified the details about the daily run control. NIBSC are expected to ask for developmental monies.
- Because of the need in the Northern Zone for a back-up filter for Plasma, Phase 1 trials on the Baxter filter will commence as soon as possible. Phase 0 trials are scheduled at the end of Phase 1. **(ACTION: AS)**.

108.5 **Blood Pack User Group**

The final evaluations, commissioning and deployment need to be completed within the next 78 days.

All trials for the baseline plan filters have now been completed and signed off. Results from the MacoPharma Phase 2 in Birmingham will be available after the next meeting of the Blood Pack User Group.

Arrangements are being made to audit the NPBI filter plan in Italy. The Baxter audit which was planned for Sept 99 will now happen in Jan 00, although Michele Ashford will still visit the plant in Sept.
(Note after meeting - Audit will now take place in Sept 99).

Haemonetics appear not to have a solution to the sporadic failures. Adjustments have been made, but no improvements have been noted. The Company are prepared to pay for 100% counting. Contingency plans centre around the COBE machines. The Baxter Amicus machine has yet to be fully evaluated. It was agreed decisions should be taken locally as to which machines will be used in the Centres.

108.6 **Finance**

The tendering process is now well under way with responses requested by 23 July. A meeting is being arranged for as soon as possible after that date for decisions to be made as to awarding 80% of the contract from 1 Nov 99.

The possibility of sending letters of intent to the manufacturers to give them maximum time to met our demands was agreed. This would also clarify the NBS thinking at Centre level. **(ACTION: SM)**.

Production Managers have been asked to lay down plans by Centre/Week to drive out the issues around ramping up. TM agreed to oversee this process. **(ACTION: TM)**.

The National Commissioning Group will receive firm prices by Nov 99 - these are expected to show a cost improvement in line with targets.

Concern was expressed as to the Manufacturers ability to meet our continuing demands for standard packs until full implementation. The National reserve of packs needs to be closely monitored in order that the NBS does not incur high wastage costs. **(ACTION: Ops Dirs)**.

108.7 **Project Administrator**

Report presented and filed with the Minutes.

109. **Risk Assessment**

All members of the LD PIB have been sent the latest Risk Analysis. Comments to NT as soon as possible please. **(ACTION: ALL)**.

110. **Blood Matters / LD Update**

The next edition of Blood Matters is due at the end of Sept 99. TW to supply an update on Leucodepletion. **(ACTION: TW)**.

111. **AOB**

TW tabled a proposal from Jerhard Seghatchian re the establishment of a NBS-wide External Proficiency Scheme for Leucodepleted blood components. This was agreed by the LD PIB. **(ACTION: TW)**.

The question of when the next round of Phase 0 trials can commence was raised. The data is required by July 00. Phase 1 trials could therefore start in Mar / Apr 00. Manufacturers will be asked to confirm their products meet our specifications before trials commence. AS will write to the relevant manufacturers for this confirmation in preparation for the Sept 99 LD PIB. **(ACTION: AS)**.

All future Agendas, supporting documents and Minutes will be sent to Neil Beckman and the Production Managers for information unless specifically requested not to do so. **(ACTION: LB)**.

At this point (12.30pm) with most of the formal business completed the meeting closed. Baxters, MacoPharma, NPBI, and Pall each presented their proposals giving assurances of their ability to meet demands. Each presentation is filed with the Project Office.

The next meeting will be held at 10.30am on 7 September 1999 at the Postgraduate Medical Centre, Queen Elizabeth Hospital, Birmingham

Notes of Meeting with Suppliers
14 July 99

Baxter - Andrew Whittaker, Andrew Bailey, Steve Milner

La Châtra

Total capacity at plant - 16 million
Current capacity to make LD products - 5 million (utilisation 3 million)
By 2001 capacity to make LD products - 9 million (utilisation 5 million)

Utilisation could be increased if some product lines were transferred to another production facility.

Asahi

Current capacity to make LD filters - 7½ million
After move in April 2000 capacity to make LD filters - 9 million
By 2001capacity to make LD filters - 19 million

The Asahi plant has Baxter as its sole customer

Contingency Plans and Disaster Planning are well advanced

Total supplies in the pipeline:

Asahi - inventory and in transit	4/6 weeks
La Châtre - UK finished goods	4/6 weeks
NBS inventory	4/6 weeks
Total stocks	10/16 weeks

Orders need to be placed by end of July for guaranteed delivery Sept - Dec 99.

MacoPharma - Chris Fowler et al

Lille

Current capacity to make LD products - 5 million (sales 2.5 million)
By 2001 capacity to make LD products - 12 million (sales 8 million)

Manufacture of LD products could be increased very easily.

Orders need to be placed 6 weeks before delivery.

NPBI - Mike Dudding, Gerrit Fransen, Giorgo Mari

Current supply w/wide - 4.5 million (3 million conventional, 1.5 million in-line)
Current supply UK - 700,000

With no investment within 3 months
Projected capacity 6.5 million in-line filters
Projected supply - UK - 1-2 million, non-UK 1-3 million

Contingency plans are well advanced.

2 sites for blood bag manufacture
2 sites for filter surface manufacture
2 sites for filter manufacture

Pall - Neil Gunn, Mike Turner, Stewart Lucas, Andrew Harrison

Covina

Sep 98	1 line/2 shifts/5 day working	3 million LD products
Jul 99	1 line/3 shifts/7 day working	6 million LD products
Feb99	New line installed	
Aug 99	2 lines/3 shifts/7 day working	10 million LD products

Current capacity - 4.3 million
Within 2 months capacity - 10 million

Orders need to be placed 8 weeks before delivery on Red Cell and Whole Blood Filters.
Autostop and Plasma filters have shorter lead times.