MEETING OF THE SNBTS MEDICAL AND SCIENTIFIC COMMITTEE
11 SEPTEMBER 1996
CONFERENCE ROOM, HQ

MINUTES

96.3.1 **PRESENT**

Dr D B L McClelland (Chair)	DBLMcC
Mr M Bruce (Secy)	MB
Dr E Follett (Items 96.3.4.1, 4.3-4.5)	EF
Prof I Franklin	IF
Dr G Galea	GG
Dr D F Hopkins (in attendance)	DFH
Dr R J Perry	RJP
Dr C V Prowse	CVP
Dr S J Urbaniak	SJU
Dr P L Yap (Item 96.3.4.1, 4.3-4.5)	PLY

APOLOGIES

Apologies were received from Prof J D Cash; Dr T Ferguson; Dr A Keel; Dr M McClelland.

The meeting started at 11.13 and finished at 14.45.

96.3.2 **MINUTES OF 23 APRIL 1996 MEETING**

Corrections to these minutes, issued with the agenda, were accepted. With these corrections the minutes were approved as a true record.

96.3.3 **ACTION CHART UPDATE**

An updated action chart is attached as appendix 1 to these minutes.

96.3.4 **TOPICS FOR DISCUSSION**

96.3.4.1 **<u>Production of Interferon from Buffy Coats</u>**

PLY introduced the subject (Paper 23/96). Key points to note were as follows:

i. <u>Informal</u> discussions had taken place with MCA who have given an indication of the measures they <u>may</u> require prior to giving approval for phase 1 clinical trials. This will include evidence of partitioning or inactivation of the CJD agent during manufacture. (The former approach is being pursued by Viragen).

The clinical trial phase will include a comparison with recombinant interferon - if the Viragen/SNBTS product fails to demonstrate clear benefits over the recombinant product, licencing approval will almost certainly be withheld.

ii. PLY indicated that a clinical trial of Welferon showed some benefits over recombinant interferon and drew the MSC's attention to SV40 contamination of polio vaccine cultured from monkey kidney cells - there was a possible association with tumor production. PLY agreed to send MB a copy of the relevant publication(s) (New Scientist) for circulation to the MSC. — PLY/MB

iii. Concerning the commercial viability of the Viragen/SNBTS product, this had yet to be tested as there was a view that pharmaceutical companies with recombinant products will simply adjust their prices to compete with the Viragen/SNBTS product. PLY advised that there is considerable demand for the product in Scotland but, as yet, no "ring fenced" money.

iv. ***The MSC agreed that the Viragen project should proceed as planned but the position would be kept under review. MB would ensure the subject was raised at the MSC in 6-9 months time.*** The content of this review would be considered in due course but could include input from PLY; RJP; I Hardie (for contractual detail) and M Thornton (for donor/PR input). — MB

v. It was noted that the Viragen President was making a presentation to SNBTS Board in October. DBLMcC to consider whether PLY should be invited to attend. — DBLMcC

96.3.4.2 **Measures to Reduce the Risks of Transfusion Transmitted Infections (Red Cell Components for Neonatal Use)**

i. DBLMcC advised that a revised proposal had been prepared which would result in a revised submission to ministers.

ii. MB to send IF a copy of the initial proposal to MSBT which was prepared by DBLMcC and Angela Robinson. — MB

96.3.4.3 **Screening for Microbiological Markers by PCR**

The policy on PCR screening (D25/96) was discussed. The following key points were noted.

i. ***It was agreed that para 5.3 of the policy document (96.402.0029.01) was inappropriate and RJP agreed to initiate the generation and issue of a revised version from which para 5.3 was deleted.***	RJP
ii. PLY advised that he had been involved in discussions with J Gillon concerning proposals that would permit lookback in instances where a plasma pool was found to be HCV RNA positive by PCR. JG had suggested that this proposal be considered by the Lab Managers Group at their meeting on 25 September 96. MB would ensure this was included in the agenda.	MB
iii. ***It was agreed that MB should draft a policy to cover actions to be taken at RTCs in the event of a plasma pool testing PCR (HCV) positive. The policy would include*** • ***a review of donor records to determine if any donor whose donation was included in the pool had subsequently been found to have seroconverted*** • ***a review of HCV testing records for the relevant donations*** • ***a review of plasma boxing records (ie to demonstrate that all HCV positive donations encountered in the relevant timescale can be accounted for and were not boxed (in error) for PFC)*** • ***the need to document all actions taken*** ***MB will discuss this initially with PFC then issue a proposal for consideration. Pending the formal policy document, the outline policy described above shall be adopted.***	MB
iv. DBLMcC will communicate the SNBTS position to Angela Robinson. It was hoped a UK position will be developed in due course.	DBLMcC
v. ***A proposed policy on pool testing for HAV by PCR, prepared by EF, was tabled at the meeting - for reference this should be numbered D25a/96. The MSC approved this policy, effective 12 Sept 96. An appropriate communication would be issued in due course.***	DBLMcC/MB

vi. PFC SOP indicates that if a pool is found PCR positive for HAV then the pool is not used for FVIII production but may be used for other products. RJP advised that whilst each such case would be considered individually and in conjunction with MCA, it is likely that if a pool was found to be PCR positive for HAV the entire pool would be discarded.

vii. GG raised the matter of sensitivity of pool testing. RJP accepted that the sensitivity was limited but indicated that the objective of pool testing was to provide an additional measure of safety by detecting those pools which contained a viral load that exceeded the viral inactivation capacity of the manufacturing process.

viii. RJP advised that >100 pools had now been tested by PCR for HAV and HCV - no positives have been found.

96.3.4.4 **Anti-HTLV 1/2**

i. EF advised that Peter Flanagan was presently collecting and aliquotting 2000 plasmas to be made available to UKBTS Centres for evaluation of test kit **specificity**. EF to confirm whether the aliquots will be in tubes, microplates or both and establish whether the screening protocol will be suitable for Abbott equipment. — EF

ii. MRU and PLY/PS had been discussing the strategy for confirmatory testing. In France and Holland, experience has shown that **anti-HTLV 1/2 indeterminates are never PCR positive and therefore do not now use PCR in their HTLV 1/2 confirmatory protocols.**

EF proposed that the SNBTS establishes its own data on the PCR status of indeterminates by testing the first 500 such donation samples by a protocol which includes PCR. Thereafter the results would be reviewed and a decision taken re PCR.

The MSC approved this proposal.

iii. It was agreed there was a need for a co-ordinated approach to plan for the implementation of anti-HTLV 1/2 screening - this would include a comprehensive costing exercise.

DBLMcC/MB to consider the co-ordination process. In the meantime, EF/PLY to identify funds required for confirmatory testing (including PCR screening proposal) and forward these to DBLMcC/MB by the end of Oct 96. — DBLMcC/MB EF/PLY

iv. DBLMcC would seek an update on progress with the implementation proposal from MSBT.

96.3.4.5 **MRU Proposal to Cease PCR Testing for HCV after 3 Negative PCR Results**

The MSC was generally satisfied with this proposal. However, GG advised that at.this year's BBTS meeting (Sept 6-9) Philip Mortimer had reported a very small number of indeterminate PCR negative donors who eventually became PCR positive. EF agreed to discuss this with Philip Mortimer and communicate the outcome of the discussion to MB for circulation to MSC. Pending a satisfactory response the proposed policy will be approved - to be confirmed at next MSC. EF MB

96.3.4.6 **EPFA Presentation to the CPMP Biotech Group**

i. RJP advised that a more recent summary was now available and agreed to send this to MB for circulation to MSC. RJP MB

ii. The findings of this study are being prepared for publication.

96.3.4.7 **Ante-Natal Anti-D Prophylaxis**

i. SJU tabled an executive summary of the economic appraisal summary - this has been numbered D31a/96.

ii. SJU has been invited to discuss the proposals arising from the economic study at a meeting of the Royal College of Obstetricians and Gynaecologists in December. Thereafter, the final position will be addressed at next years consensus conference.

iii. ***SJU proposed and MSC agreed that if Obstetricians wish to initiate ante natal anti-D prophylaxis for primigravidae, this should be supported by SNBTS and the dose (at present) should be 2 x 500 IU vials. This policy should be communicated to relevant parties by MSC members.***

iv. CVP advised that QHM Hospital were planning to initiate the ante-natal prophylaxis policy. This represented an additional 600 x 500 IU vials per year (100% increase). ALL

v. SJU reported that arrangements were in hand to increase the collection of anti-D plasma for fractionation to satisfy the anticipated increase in demand. SJU to prepare an update report for next MSC. SJU

vi. It was agreed that ante natal screening procedures for RhD neg prims would need to be modified.

SJU had collected data on ante natal blood group antibody screening practices in Scotland and would send a summary with recommendations on screening protocols to MB for circulation to MSC. — SJU/MB

MB would advise NRU of the position and initiate discussions on the provision of suitable antibody screening cells for use in this application. — MB

96.3.4.8 **"Red Book" Working Party on Peripheral Blood Stem Cell Harvesting from Volunteer Donors**

i. The MSC supported the recommendations contained in the paper prepared by IF (D32/96) and noted that Rachel Green is presently preparing a business case for SNBTS to include molecular typing for Class 1 and class 2 antigens. DBLMcC, CVP, IF and RG to discuss the business case and prepare an action plan. — DBLMcC/CVP/IF/RG

ii. IF agreed to update the MSC when further significant issues emerge from BBMR. — IF

96.3.4.9 **CJD**

This item was deferred until the next MSC when J Gillon will be invited to present a report on the lookback protocol/study.

96.3.5 **MATTERS FOR NOTING**

96.3.5.1 **Archive Samples**

It was agreed that once the proposals concerning the provision of samples for lookback following HCV PCR pool testing were settled, the "indefinite" policy on archive sample retention would be reviewed. MB to keep on agenda. — MB

96.3.5.2 **Red Book Executive**

i. Unanimous concern was expressed that funding problems had substantially delayed publication of the Red Book. DBLMcC agreed to write to Bill Wagstaff with proposals as to how this could be avoided in future (eg direct funding from UKBTS). — DBLMcC

ii. IF suggested the Red Book may be of relevance to hospital blood banks (eg it is used as a reference text for storage of blood and blood products at CPA Inspections). DBLMcC to raise this with the Executive. — DBLMcC

96.3.6 **AOB**

96.3.6.1 **Recombinant Factor VIII**

CVP advised the SNBTS had now signed a contract for the procurement of recombinant factor VIII. Members were asked to note that this would have supply and demand implications.

96.3.6.2 **HPIX**

A problem had been reported from GRI with HPIX (currently undergoing clinical trials) which was manifest as an apparent precipitation (excessive shaking was thought to be a possible cause). This will be discussed with the Haemophilia Directors at a meeting on Friday (13 Sept).

96.3.6.3 **VIP**

i. DBLMcC/CVP reported on a special SACTTI meeting on 10 Sept 96 which was concerned with VIP.

Octopharma are expected to have a licenced product available in the UK before the end of 1996. Consequently, there is a need to consider:

- what advice BTS medical staff give on the use of VIP vs traditional FFP?
- what is our public position?
- what action do we take?

ii. It was agreed that:

- the SNBTS was actively pursuing a strategy aimed at reducing risk to recipients of plasma components. This included the use of accredited donors and the development of fibrinogen concentrate.
- RJP would produce a position paper, including costs and proposals, with input from CVP, outlining options in terms of technology, manufacturing site, resources and timescale. To be submitted to DBLMcC/MB. — RJP

96.3.7 **DATE, TIME, VENUE NEXT MEETING**

17 December 1996, 10.30am. SNBTS Conference Room.