MEETING OF THE SNBTS MEDICAL AND SCIENTIFIC COMMITTEE
10th NOVEMBER 1994
AT CONFERENCE ROOM, SNBTS HQ

94.3.1	**Present**	Prof J D Cash (Chair)	**JDC**
		Mr M Bruce (Secy)	**MB**
		Dr E Brookes	**EB**
		Dr E Follett (items 94.3.5.5 & 3.5.6 only)	**EF**
		Dr G Galea	**GG**
		Dr D F Hopkins (in attendance)	**DFH**
		Dr A Keel (items 94.3.1, 3.2, 3.4.1-3.4.3 only)	**AK**
		Dr S Lumley (item 94.3.3.3 only)	**SPL**
		Dr R Mitchell	**RM**
		Dr D B L McClelland (from 1.1.2.5)	**DBLMcC**
		Dr M McClelland	**MMcC**
		Ms J Pelly (item 94.3.3.1 only)	**JP**
		Dr R J Perry	**RJP**
		Dr C V Prowse	**CVP**
		Dr S J Urbaniak	**SJU**

The meeting started at 1050 and finished at 1625.

94.3.2 <u>MINUTES OF THE 17th AUGUST 1994 MEETING</u>

The corrections to these minutes (issued with the agenda) were approved. Correspondence from RJP of 09 November 1994 (attached as appendix 1) requested that the following were recorded as addenda to minute 94.2.5.3:

a. "that the use of NBA plasma in the manufacture of PFC products had no public health implications ie no risk to patients".

b. "that the PFC Director strongly opposed the view that there had been a quality system failure and that there was evidence of full compliance with all quality systems and specification currently in place".

The MSC agreed that RJP's views as shown in a & b above should be assimilated into the record of the 17 August 1994 meeting.

With these corrections registered it was agreed the minute was a true record of the 17 August 1994 meeting.

94.3.3 **MATTERS ARISING**

1. **INVOLVEMENT OF SNBTS CLINICIANS IN TRIALS, ADVICE AND PROMOTION OF PFC PRODUCTS**

CVP introduced this topic. JP was present to field questions that arose. Key issues were as follows:

i. There was consensus that this approach and wording used required sensitivity and caution. Specifically , reference to "marketing" and "advocate clinician" caused concern and should be deleted.

ii. The corollary to this was the consensus view that SNBTS (PFC) products should have available the level of information and support that users were entitled to expect. eg RJP felt that Belfast RTC were not receiving the level of support that they were entitled to expect and CVP agreed to look into this. CVP/JP

iii. It was agreed that RTDs would be contacted to establish which clinicians should be involved in the process. CVP/JP

iv. JP was given approval to proceed with this process. The next step would be to contact RTDs as per iii (above). Thereafter, CVP will advise a date for the next report (about 6 months). CVP

2. **RhD GENOTYPING**

SJU provided a verbal update. Key points were as follows:

i. The technique (in general) was still in development and results could be unreliable.

ii. With respect to the current developmental nature of this test, there were international concerns about observed discordance between PCR and conventional serological test results. This discordance might impact on patient morbidity and mortality

iii. NERTC had validated their test procedures and were presently investigating the reliability of available primers in conjunction with other international Centres.

iv. In view of the above, NSL would not be testing clinical samples.

v. NERTC invited colleagues to refer test samples. The agreed referral/reporting line was between the referring RTC and NERTC. This "service" could currently be maintained without charge to RTCs.

vi. WRTC also were using this technique.

vii. There appeared to be no collaboration between W/NERTC in this area and an opinion was expressed that this should be encouraged.

3. PCR TESTING OF BONE AND TISSUE DONORS

SPL summarised her paper (D13/94) which supported her proposal that "PCR testing is justified for non-living tissue donors".

This promoted useful discussion, the key points of which were as follows:

i. there was unanimous support in principle for PCR testing of non-living tissue donors but that it was not yet an opportune time for Centres to implement.

ii. it was agreed that the risks/costs of not testing needed to be more accurately defined.

In this respect, it was agreed that JDC would identify the means by which this might be achieved. AK ~~offered to~~ agreed to provide any ~~reasonable support via~~ information available through UKTSSA, if approached. — JDC/AK

iii. it was understood that the MSBT subcommittee on this matter was about to release a report that would indicate that PCR was not an appropriate test for non-living tissue donors.

When available, this document would be commented on.

iv. It was agreed that a schedule for SNBTS implementation must be worked out in due course and it was noted that NBA did not yet have a formal policy/commitment to tissue banking.

4. ACCREDITED FFP/CRYO (CLINICAL USE)

4.1 SNBTS Feasibility

i. Paper D14/94 was discussed. This had been a useful start to the process but several members wished to have further discussions/input. DFH to liaise as — DFH

appropriate with RTD & PFC colleagues and bring forward a revised document.

ii. Several members had noted that computing could be a major problem. DBLMcC indicated he had asked Mike Moores to work with the SERTC CSM to sketch out the computer requirements for this change. This was tabled at the meeting and is attached as appendix 2 to the minute.

JDC to write to D Morris, advising him that Mike Moores was assisting with this process. JDC

iii. RJP cautioned against building up an excess of "accredited" cryo in advance of the anticipated introduction of a fibrinogen product. This was noted.

4.2 **UKBTS Policy**

i. JDC advised that the introduction of "accredited FFP/cryo in the UK had been approved in principal but that the detail of implementation dates, costs etc still had to be worked out.

ii. With respect to the manufacture of clinical FFP and cryo only from repeat donors, it was agreed that notification should be given of an appropriate, UK wide effective date. As a preliminary, it would be necessary to establish whether such a change would impose any special limitations on the effective date. MB to pursue for SNBTS/NIBTS. JDC would contact Angela Robinson to establish the NBA position. MB JDC

5. ALT TESTING

i. JDC advised the Committee that he had consulted Angela Robinson to establish the current state of play. The information was that the MSBT had considered this matter and concluded it had nothing to do with blood safety.

ii. It was noted that the matter now would be referred to Ministers for consideration but that all 4 will have to agree to proceed with ALT testing before it can be introduced.

6. HCV LOOKBACK

i. JDC advised he had contacted Angela Robinson to establish the current position. The information was that the MSBT had some problems with the original proposals.

Angela Robinson, with two other clinicians, had been asked to bring forward a revised document. This was in progress.

ii. With respect to the meeting which took place in Edinburgh with BTS and hepatologists, JDC advised that very positive reactions and support for the programme had been received by clinicians.

iii. On a point of principle, it was noted that the lookback study published by Jack Gillon in Transfusion Medicine resulted from a SERTC R&D project and was not a study commissioned by the RTDs. JDC would advise JG of this fact. JDC

iv. It was agreed that SNBTS RTCs can commence the programme but only to the point, at this time, of gathering data sufficient to identify patients at risk.

7. **ARRANGEMENTS FOR DEALING WITH PREVIOUSLY NEGATIVE, REPEAT REACTIVE DONORS**

The Committee agreed that this merited further investigation and more detailed consideration. MB to investigate and report back to next MSC. MB

8. **ABBOTT ANTI-HIV1 PLUS 2, 3rd GENERATION PLUS EIA KIT**

i. COR/MRU had now completed their evaluation of this kit. It was agreed that in the absence of HIV-O positive samples for SNBTS evaluation, this kit could not be recommended for use in the detection of HIV-O.

ii. JDC would review data concerning improved sensitivity for anti-HIV1 & HIV2 with this kit. If a clear improvement was evident, an effective date on which SNBTS Abbott users would switch to this kit (for anti-HIV1 & HIV2) would be advised. JDC

iii. The final report/decision would be communicated to Abbott. JDC

iv. It was noted that with respect to the evaluation of the Murex kit for the detection of anti-HIV1+2 +O, being undertaken at SERTC under COR co-ordination, 2 batches of these kits will be evaluated for sensitivity at MRU.

v. The SNBTS will not introduce kits that claim to detect HIV-O until/unless
   - the sensitivity for anti-HIV1+2 is not reduced
   - the specificity characteristics equal or exceed those of existing kits for anti-HIV 1+2
   - the SNBTS has access to anti-HIV-O positive samples to independently validate manufacturers' claims.

94.3.4 **ITEMS FOR NOTING**

1. **SNBTS Tissue Banking Group**

i. The Committee acknowledged SJU's contribution as chair of this Group and invited GG to take over the chairmanship. This invitation was accepted.

ii. It was agreed that this chairmanship should be for an initial 3 year period with the option for extension if MSC/GG consider this appropriate.

iii. GG would consider whether to revise the broad remit to which the Group presently was working. GG

2. **Increased Donation Volume/Faints**

i. GG was asked to collate information on donor faints via the Donor Consultants Group and forward this to MB. GG

ii. It was agreed that this study should be published. MB/GG

3. **Sexual Partners of HCV Positive Individuals**

It was agreed that the paper being prepared by Jack Gillon on behalf of the SNBTS Donor Consultants Group should be submitted to the SAC on Care of Blood Donors (not SACTTI). MB to confirm this with JG. MB/JG

4. **BCSH Task Force: Informed Consent for Transfusion**

DBLMcC advised that this matter is being addressed in the latest revision of the Handbook of Transfusion Medicine.

94.3.5 **AOCB**

1. **Viral Inactivated Plasma: Methylene Blue**

CVP updated the Committee on the process being developed by Baxter from the Springe procedure.

Baxter will provide special packs with an in-line filter and containing 10mL methylene blue (PL 732 plastic). These pack configurations are patented.

The plasma/methylene blue mixture will be irradiated using irradiators from Baxter which take 2 packs of plasma. Irradiation is for 20 minutes ie at present, 6 packs/irradiator/hour. CVP will keep the Committee informed of progress, particularly with respect to the potential for SNBTS involvement in field trials. CVP

2. **PDG Activities**

RM had expressed concern that the PDG minutes did not provide sufficient detail. RJP suggested that a regular "roadshow" approach might provide a useful vehicle by which to improve communications. RJP/CVP to explore and implement, if appropriate, and possible. RJP/CVP

In the interim, CVP would arrange to brief RM. CVP

3. **PCR and Patents**

CVP advised that the Scottish Office presently were in discussion with Roche and ~~were developing~~ a draft licence agreement to cover NHS in Scotland use of PCR. Until this has been concluded and communicated, no local agreements were to be signed.

4. **Tissue Banking/SEBTS**

re 94.2.4.3iv (agenda) Proposals for a South of Scotland Tissue Bank. DBLMcC provided the following clarifications.

i. Due to lack of space on the RIE site, and increasing pressure to ensure provision of a secure and effective service for heartvalves (and bone), SE had identified an acceptable site at PFC.

ii. This PFC (pilot plant) site is presently being developed as a clean room for NRU. Once NRU relocate to new premises the area will be available for tissue banking.

iii. Mr Francis requested the MSC's views in a capital bid received from the SEBTS on a "South of Scotland Tissue Bank". This had been considered at the August 1994 meeting and in the form presented and due to the absence of Dr McClelland has been "put on ice".

iv. A revised project for a SERTC tissue bank, not a "South of Scotland" tissue bank commited to the programme previously agreed by MSC in 1992/93 was discussed and supported.

v. The funding requirements for this revised SE project have been reviewed and substantially reduced from that considered by MSC (August 1994). (DBLMcC advised the capital cost was £100,000).

vi. Approval to proceed with the revised (ie SERTC) project had been granted at the latest Board.

vii. The MSC has not yet advised a change of SNBTS policy with respect to cadaver donors ie this remains an approved procedure for cardiac valves in SERTC only. Any policy change will be considered against proposals that arise from the paper presently being prepared by JDC.

5. <u>Testing Requirements "Booster Red Cell" Donors</u>

EF joined the meeting at 15.50.

i. It was agreed that since these donors were being screened for anti-HBc there was no need to test for anti-HBs. This change will be made at the next revision of this procedure. — SJU

ii. PLY had asked whether use of PCR might reduce the number of available red cell donors for this programme. EF/SJU/PLY will be meeting to discuss and develop proposals. — EF/SJU/PLY

6. <u>Arrangements for Reinstatement of Anti-HCV Repeat Reactive Donors</u>

i. MRU presently were receiving numerous referrals for donors who were previously anti-HCV repeat reactive, RIBA indeterminate (1 band) but now produced negative ELISA screening results. EF proposed that in such circumstances, MRU would test these samples in ELISA with Abbott, Murex and Ortho kits. If all 3 kits produced a negative result, the donor would be eligible for re-instatement.

ii. The Committee approved this proposal in principle. MRU/COR/Donor Consultants to work up an appropriate "SOP" before an implementation schedule is advised. An outline flowchart was tabled and is included as appendix 3. — RM/EF/GG/JDC

iii. JDC would keep the NBA and other appropriate parties informed of the SNBTS position. JDC

7. **Hyperimmune Plasma**

JDC/GG

JDC expressed a view that the Donor Consultants Group should keep a watching brief on developments in the use of specific immunoglobulins in addition to considering demand. JDC to discuss with GG.

8. **Genetic Technology**

CVP advised that the report "NACSS Report on the Service Application of Molecular Technology - a Framework for the Future" was due for publication and now incorporated SNBTS activities in this area.

94.3.6 **ACTION CHART UPDATE**

An updated action chart is attached as appendix 4.

94.3.7 **AGENDA PLANNER**

An updated agenda planner is attached as appendix 5.

94.3.8 **FUTURE MEETINGS**

08 February 1995)
16 May 1995) 10.30am start
10 October 1995)
09 January 1996)

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