NOTE OF AN SNBTS MEDICAL AND SCIENTIFIC MEETING
17 DECEMBER 1996
CONFERENCE ROOM, HQ

MINUTES

96.4.1 **PRESENT**

Dr D B L McClelland (Chair)	DBLMcC
Mr M Bruce (Secy)	MB
Dr B Cuthbertson	BC
Prof I Franklin	IF
Dr G Galea	GG
Dr A Keel	AK
Dr M McClelland	MMcC
Dr R J Perry	RJP
Dr C V Prowse	CVP
Dr S J Urbaniak	SJU

DIRECTOR'S OFFICE
Date Received 31/12/96
Date Actioned
Action Taken
File No.

APOLOGIES

Apologies were received from Drs Gillon, Yap and Simmonds.

96.4.2 **VIRAGEN**

96.4.2.1 DBLMcC provided a verbal update. The key points were that SERTC would continue to develop a component separation process that would satisfy SNBTS specifications and provide suitable buffy coats for interferon production.

96.4.2.2 It was noted that other RTCs would not be involved in the process until mid-summer 1997.

96.4.2.3 The SE team will be nominating an individual to develop optimal component production processes and co-ordinate their introduction across the SNBTS. Funding for this post will be sought from Viragen. DBLMcC

96.4.2.4 **The SNBTS Board had agreed that arrangements would have to be made to guarantee continuity of supply for the buffy coat depleted components that would result from the provision of buffy coats for Viragen ie if the Viragen project fails.**

96.4.2.5 **Regarding financial provision for the introduction of buffy coat production in other RTCs - each Centre will have to produce business proposals to include contingency funding.** JF

96.4.2.6 **DBLMcC agreed to co-ordinate the production of a project status report with RJP and Peng Lee Yap (PLY).** DBLMcC

This would be made available to AK by the end of January 1997.

96.4.2.7 With respect to item 96.3.4.1iii of the last MSC minute, AK advised that "ring fenced" funding for interferon treatment would **not** materialise.

96.4.3 **MICROBIOLOGY TEST KIT EVALUATIONS**

96.4.3.1 **UK Position**

1. AK indicated there had been an internal meeting at MDA on the development of a UK kit evaluation scheme and agreed to provide MB with details. — AK

2. **The conclusions in MB's paper (D33/96) were noted and the following were agreed:**

   i. **There was unanimous support for the development of a UK kit evaluation process.**

   ii. **DBLMcC would write to MDA and to MSBT to put forward the case for such a process. This would indicate that approval through this process was a prerequisite for including a test kit on a fractionation Centre's Plasma Master File.** — **DBLMcC**

   iii. **DBLMcC would write to Dr Robinson to attempt to consolidate the involvement of the SNBTS in the NBA scheme and vice versa. This will include continuing reciprocal attendance at meetings of the respective kit evaluation teams and an agreement that addition of any kits to the "NBA/SNBTS Approved List" will be by mutual consent.** — **DBLMcC**

   iv. **As an interim measure, it was agreed that the listings of SNBTS and NBA approved kits and BPL/PFC plasma master files would be compiled. These would then be exchanged with the NBA to ensure the lists are compatible.** — **MB**

96.4.3.2 **SNBTS Kit Evaluation SOP**

In view of the expectation that a new Director of NMRU will be appointed and that this will allow a simplification of the SOP, DBLMcC proposed that the procedure be

revised and a draft made available for comment at the next meeting. The revision process would take account of whether the procedure should cover plasma for fractionation. This was agreed. **MB**

96.4.3.3 **SNBTS Specification of Plasma for Contract Fractionation**

i. **It was agreed that this was of fundamental importance to the organisation and that any policy proposals would need the approval of SHHD professional advisors.**

ii. **The Group were asked to send BC comments on the policy as soon as possible - preferably before the end of the week (ie 20 Dec 96).** **ALL**

iii. **It was agreed that the objectives of the policy should be:** **BC**
- **to protect the integrity of PFC and the safety of its products**
- **to assure the safety of contract fractionated products**
- **to be acceptable to the SHHD**

iv. **BC would highlight the differences between the SNBTS plasma specification and that proposed for contract fractionation and send to DBLMcC.** **BC**

v. **Re the Ukraine project, DBLMcC will request SCIEH, to assemble any available evidence about the epidemiology "map" of blood transmissible infections in Ukraine in general and the sites of the three apheresis centres in particular.** **DBLMcC**

vi. **DBLMcC and RJP will prepare a full briefing for AK that will form the basis of a briefing for SHHD.** **DBLMcC/RJP**

96.4.4 **CJD LOOKBACK**

At the request of MSBT, Drs Gillon and P Hewitt have developed a protocol for a limited CJD lookback. This has been approved by MSBT and is being implemented on a UK wide basis.

96.4.5 **HEPATITIS G EPIDEMIOLOGY**

A pilot study is going ahead in SEBTS whereby 1000 donor:recipient "pairs" will be established. Pre and post (x2) transfusion samples will be screened by PCR. The pilot has MSBT approval and funding may be available to allow other interested Centres to participate. Interested parties to contact DBLMcC. **ALL**

96.4.6 **DEVELOPMENTS IN THE USE OF PCR FOR DONATION SCREENING**

96.4.6.1 RJP provided the following report:

i. A further meeting of EPFA and EAPPI with the CPMP is scheduled for Feb 97. At this meeting it is expected that EAPPI will propose the introduction of PCR testing of pooled apheresis plasma for fractionation (and probably minipools) for all mandatory markers.

ii. EPFA members generally face additional complications due to the production of "fresh" blood components with the consequent need for online testing to avoid release of components that may subsequently be found to be PCR positive.

iii. Single donation PCR screening will be evaluated in a large scale trial in Germany and there is some expectation that this will become a mandatory requirement in Germany.

iv. If the maximum detection capability of PCR is exploited screening of PFC pools will produce occasional positive results. To minimise the risk of loosing an entire pool, PFC will need to develop a minipool screening protocol.

v. BPL have now had 3 pools PCR positive for HCV RNA with resultant loss of 3 complete fractionation batches at a cost of several million pounds. Consequently, with a proposed start date of April 97, on receipt at BPL, an unlabelled line sample will be taken from all plasmas prior to placing the plasma donations into a cage. Each cage holds 800 plasmas and the plasma line samples will be pooled and screened by PCR. In the event of a negative result the plasma will be released for fractionation. If a positive PCR is obtained the whole contents of the cage of plasma will be destroyed. No attempt will be made to identify the implicated donation(s) in the pool. There will be no lookback procedure. This runs counter to the majority EPFA view and the unanimous view of this Group.

vi. **Pressure from Germany on the CPMP may well lead to a requirement for PCR screening as a part of the release procedures for fresh blood components. There is no indication that existing serological tests will be dropped.**

96.4.6.2	Dr P Simmonds has developed a technical approach that could allow rapid testing of single donations for a group of viruses. The operation details and costs have still to be explored.	DBLMcC
96.4.6.3	**The paper produced by PS will be circulated with the minute and proposals for a pilot study will be submitted to the Board in Feb 97. It was agreed that this matter would be presented for future discussion once the operational problems arising from the intended approach had been considered.**	
96.4.7	**PFC PRODUCT RETURN SOP**	
96.4.7.1	It was agreed that SOP 96.111...01 did not address the difficult issue of determining the extent to which cold chain integrity in hospitals could be assured.	
96.4.7.2	**DBLMcC will draft a suggestion for some practical points which should be applied in this situation and will send this to MB/BC.**	**DBLMcC**
96.4.7.3	**MB/BC will meet with Mr W Hughes to consider how best to respond to the issues raised by MCA and will produce a report for SNBTS Board outlining the most appropriate action and its financial and operational implications.**	**MB/BC**
96.4.8	**SNBTS POLICY ON PCR SCREENING FOR HCV AFTER 3 NEGATIVE PCR RESULTS**	**EF**
	The Group agreed to introduce a policy whereby donors who are screening test repeat reactive, RIBA indeterminate and who are consistently PCR negative need only be tested for PCR on 3 occasions. Effective date for this policy 23 Dec 96.	**ALL/MB**
96.4.9	**SNBTS POLICY ON HAV**	
	It was agreed that BC will amend the SNBTS (PFC) policy on PCR testing to confirm that there is no requirement or scientific rationale for lookback on HAV positive plasma pools.	**BC**
96.4.10	**SNBTS POLICY ON MRU TESTING OF SAMPLES FROM DONORS CONFIRMED TO BE POSITIVE FOR MANDATORY MICROBIOLOGY MARKERS**	
96.4.10.1	It was agreed there should be an SNBTS approach to this process, indeed it was acknowledged that Transform will require it!	

96.4.10.2	**GG agreed to draft an SNBTS policy to govern this activity. To be sent to DBLMcC/MB by mid Jan 97**	**GG**
96.4.10.3	MB was asked to write to Dr B Dow to update him on the actions resulting from his enquiry.	MB
96.4.11	**PROPOSALS FOR SNBTS PROFESSIONAL POLICY MAKING**	
96.4.11.1	IF expressed the view that the suitability of the proposal would largely be determined by the structure of the SNBTS Board ie if the SNBTS Board had adequate representation from Operational Units, the proposals in paper D41/96 would be acceptable. Otherwise there would be concerns. This view was supported by the majority of those present.	
96.4.11.2	With the proviso outlined at 11.1, the Group were unanimous that the proposals in paper D41/96 should be supported.	
96.4.12	**REAGENT RED CELLS: LISS: NRU**	
96.4.12.1	MB advised that >98% of NEQAS respondents (n > 440 approx) now use LISS techniques but, with the exception of Diamed, no reagent manufacturers produce LISS suspended cells (and Diamed apply an alternative approach to LISS methodology). Therefore it can be deduced that the majority of UK blood banks covert antibody screening panels to LISS. Since LISS methods (as judged by NEQAS) have demonstrably improved sensitivity over NISS, presumably the process of users converting NISS cells to LISS is working effectively and there is no reason to suggest this conversion is problematic.	
96.4.12.2	It was agreed that there were various options to advance this matter in a manner that would satisfy CPA.	
96.4.12.3	**MB will liaise with SJU and Mr J Allan on the best way forward on an interim basis.**	**MB/SJU**
96.4.13	**ANTI-D IMMUNISATION**	
96.4.13.1	DBLMcC reminded the group of the audit of this process in 1994 and the MSC decision that the audit should be repeated in 1996. This repeat audit had not taken place.	
96.4.13.2	A process of formalising procedures in this area on a National basis had uncovered the fact that: • West RTC had not implemented anti-HTLV1 screening in the donation accreditation process (red cells from West donors were being held pending anti-HTLV1 screening)	

- there were no written procedures to govern the accreditation and release process
- that SERTC also held a stock of frozen red cells for this purpose which were not on the national register (which is held by NERTC).

96.4.13.3 **MB was asked to give priority to resolving these matters and to arrange a repeat audit of the process before the end of March 1997.** — **MB**

96.4.13.4 GG indicated that there were other problems which the 1994 audit did not uncover and agreed to communicate these to MB. — **GG**

96.4.14 **VIRUS INACTIVATED PLASMA**

DBLMcC provided an update - MSBT had received a proposal on this matter and had established a working party (Andre Rejman, RJP and Terry Snape) to progress the issue. A briefing for the February or March 97 Board is essential. — **DBLMcC**

96.4.15 **NMRU DIRECTOR**

DBLMcC advised that in November the SNBTS Board had approved a proposal concerning the post of NMRU Director which would be filled at Consultant/Senior Lecturer level. The postholder will have accommodation in the University of Edinburgh and will be required to bring relevant proposals for the future of MRU. — **DBLMcC/MB**

The post will be advertised on 23 Dec 96 and DBLMcC agreed to provide a copy of the job description and NMRU proposal to be circulated with the minute.

96.4.16 **AOB**

96.4.16.1 **Transfusion Transmitted Infection Litigation**

DBLMcC advised that Susan Murray from CLO has been nominated to prepare the defences on pending HCV cases. Ms Murray will be seeking assistance of RTDs to ensure that all potential litigants already known to SNBTS are listed.

96.4.16.2 **DEFIX**

RJP advised that this product has received its MCA license for use in Warfarin reversal.

96.4.16.3 **National "Medical and Scientific" Cover**

DBLMcC left the meeting for this item.

The Group discussed the difficulties which would arise in the interval between DBLMcC stepping down as Acting NMSD and the appointment of a NMSD. Numerous reasons were given in support of the view that the use of nominated individuals would be unsatisfactory.

There was unanimous support for the view that the various responsibilities should be discharged by a single, appropriately experienced Medical Consultant.

96.4.17 **FUTURE MEETINGS**

MB was asked to schedule two further meetings of this Group for 1997. MB