SNBTS MEDICAL AND SCIENTIFIC COMMITTEE MEETING

23 April 1998 at 10.30 am
Board Room, Headquarters

MINUTE

98.3 1.1 **PRESENT**

Professor IM Franklin	(Chair)	IMF
Mr M Bruce	(Secretary)	MB
Dr B Cuthbertson		(for RJP)
Dr B Dow		BD
Dr E Follett		EF
Dr G Galea		GG
Dr R Green		RG
Dr M McClelland		MMcC
Dr CV Prowse		CVP

98.3 1.2 APOLOGIES

Apologies were received from Dr T Ferguson; Dr J Gillon; Dr DBL McClelland; Dr RJ Perry; Dr SJ Urbaniak.

98.3 1.3 MINUTES OF 05 MARCH 1998

The minutes of the 05 March meeting were approved as a true record

98.3 **2 MALARIA**

98.3 2.1 MSC agreed that the approach described in the previous minute should be introduced - ie commence an evaluation of the malarial antibody test (MAT) and set this up in Progesa but extend the 'deferral' period for components for direct clinical use to 12 months and perform MAT at each visit.
BD to produce a review of the trial, to be considered by the MSC around 9 months after implementation, ie will report to MSC around January 1999. On receipt of trial report, MSC will decide whether re-instatement of MAT negative donors would be introduced for SNBTS. **BD**

98.3 2.2 It was noted that if UK plasma was to be banned for use in fractionation (as is expected in an announcement from the Committee on the Safety of Medicines around 30 April 1998), then failure to introduce a MAT would result in the permanent loss of some "malarial" donors.

98.3 2.3 BD had produced and tabled a request form for MAT (D36/98 for reference purposes) and MSC were invited to send comments within 2 weeks. BD to revise the request form accordingly. **ALL**

98.3 2.4 MB to submit a parameter table change request in line with the MSC decision. **MB**

98.3	3	HCV	
98.3	3.1	HCV LOOKBACK	
	3.1.1	JG had prepared an updated summary on the Scottish position to date and this was tabled at the meeting (D37/98 for reference purposes).	
	3.1.2	IMF had written to Dr Keel at SOHD and Dr Burns at GGHB but had not received a reply. IMF proposed he write again to Drs Keel and Burns, providing them with a summary report of the SNBTS position. This summary report to include information on lookback on PCR negative, RIBA indeterminates - of which all recipients studied to date (all RTC except W RTC, around half) had been PCR negative.	**IMF**
	3.1.3	IMF to invite SOHD / GGHB to consider this summary report (98.3.3.1.2) and advise SNBTS whether it wishes to provide additional resource in support of one final effort to conclude every single case or, alternatively, considers SNBTS has done everything possible to conclude the exercise, in which case the file will be closed.	**IMF**
98.3	3.2	PCR POSITIVE, SERONEGATIVE DONORS AND RECIPIENTS OF THEIR COMPONENTS	
	3.2.1	IMF had written to and received a reply from Dr Hewitt regarding the NBA approach to lookback for such cases (D27/98). NBA will use their standard lookback procedure.	
	3.2.2	MSC noted that NBA would be asking the CMO to write to all doctors, to advise them that the NBA would be initiating PCR screening of donors for HCV RNA which would very rarely result in the need for lookback to recipients of PCR positive, serology negative recipients. MSC considered this policy excessive but IMF would contact the Scottish CMO to enquire whether he would wish the NBA approach would be followed in Scotland.	**IMF**
	3.2.3	EF had received a reply from Dr Dusheiko (D27/98) which was discussed by MSC. The Committee agreed that the SNBTS approach to lookback would include early referral to an appropriate hepatologist. MB to record this policy.	**MB**
	3.2.4	RG enquired whether funding for on-going lookback (re PCR) had been included in the PCR budget or in PES. It was agreed this should be included within the PES discussions to take place later in the agenda.	
	3.2.5	Re SNBTS policy on PCR testing and lookback, MB/CVP to bring forward proposals to next MSC.	**MB /CVP**
98.3	3.3	HCV PCR POSITIVE PLASMA POOL	
		MB updated MSC on progress with resolving the above pool to a single donation. Contributing donations were from West RTC (n=4287); North East RTC (n=760) and South East RTC (n=216). To date, all three RTCs had complied with policy set out in MSC 96.3.4.3.iii. A protocol has been developed to prepare subsamples of the sample archives and test minipools of 95 samples in the first instance, results will be communicated to MB and to affected RTDs, and QA/Lab Managers.	

NMRU are involved in the process as is CVP. An attempt will be made to identify the full costs of the exercise. Sub sampling and testing the archive will take 6-8 weeks minimum.

98.3 3.4 NATIONAL REGISTER / INFECTION SURVEILLANCE

3.4.1 The relevant documents were discussed (D28/98). (Papers tabled at the meeting have been lodged as D38/98). With regard to the National Register, IMF will write to Dr Flanagan to request that this item be discussed at the forthcoming SACTTI meeting. SNBTS concerns about confidentiality remain and MSC would wish to operate in a mode whereby SNBTS inputs information to the system and anonymous data are passed to SCIEH for interaction with the PHLS system. **IMF**

3.4.2 Re Infection Surveillance:

3.4.2.i The forms drafted by B Dow were discussed and minor amendments suggested. B Dow to action (eg remove donor's name). **BD**

3.4.2.ii GG had the last 3 years of SNBTS epidemiological data and would send this to BD. **GG**

3.4.2.iii BD and EF will use the data described at 3.4.2.ii above to retrospectively complete the proposed infection surveillance forms from 01 January 1998. BD and EF will assess the workload and, unless excessive, will put all data onto the new forms. **BD/EF**

3.4.2.iv BD will produce an annual report on this exercise for MSC by end March each year. **BD**

3.4.2.v It was agreed that once compiled, the data may be made available to SCIEH. IMF to discuss at SACTTI. **IMF**

3.4.2.vi The importance of collecting appropriate information on possible transfusion transmissions and their investigation was agreed (re SHOT). It was agreed that on being notified of such cases, Centre medical staff would complete form (ah) 0\SNBTS - 15\19.02.98 included within D28/98.
BD/MB to develop an SOP. **BD/MB**

98.3 4 SNBTS POLICY STATEMENTS

98.3 4.1 NEW DRAFTS

4.1.1 D29/98 was discussed and changes noted by MB for action. Additional points are recorded below.

4.1.2 Re bleed time, it was noted that Dundee and Aberdeen currently use a bleed time cut-off of 10 minutes; Inverness 12 minutes vs the national maximum limit of 15 minutes.

4.1.3.i Re leucodepleted components for neonates, it was noted that the recently published BCSH guidelines (Transfusion Medicine 8; 59-71; 1998) recommends that pregnant patients should receive leucodepleted components. MB to ensure this topic is on the next MSC agenda. **MB**

4.1.3.ii Re leucodepleted components for neonatal use, it was agreed that demand should be re-assessed after two months experience. (ie -

end of May 1998).

4.1.4 Re evaluation of the SNBTS PCR testing system, it was agreed that the SNBTS Kit Evaluation Group be renamed the SNBTS Microbiology Testing Evaluation Group. BD to action. **BD**

98.3 4.2 VIRUS TESTING ON CLINICAL TRIALS

MB agreed to clarify and revise the proposed policy to indicate that: **MB**

- any plan to test for virus markers other than those required by MCA must be on the basis that there is a reason to believe the agent may be transmitted by the product under trial and must be agreed, in writing, by NMSD;
- if a patient tests positive for a virus marker before entering the trial, that patient would be excluded from seroconversion studies for that marker;
- if the marker is mandatory, SNBTS may undertake an investigation;
- if the marker is not mandatory, SNBTS will not normally investigate.

98.3 4.3 MANDATORY MARKER REPEAT REACTIVE, REFERENCE LABORATORY NEGATIVE

4.3.1 GG explained that a new deferral code had been set up in Progesa to facilitate monitoring of this condition.

4.3.2 The following 'policies' were being applied:

- East and North East RTCs, counsel the donor and put off-service after four repeat reactives;
- South East and Belfast RTCs use a cut-off of six repeat reactives.

4.3.3 It was agreed that BD would examine the number of repeat reactive donations around the cut-off etc. Donor Consultants to use BD's data to draft a policy, including recommended cut-off number (with exceptions as appropriate), for next MSC. **BD** **GG**

4.3.4 As an interim working arrangement, MSC agreed that Centres could adopt a policy of putting these donors off-service after four repeat reactive donations.

98.3 4.4 C1 ESTERASE

RG summarised the present position - ie previously, WRTC have held a small stock of this very low demand product which they have made available, free of charge, on a national basis. The present product is from CLB and is not fully licensed - MSC agreed SNBTS should discontinue supply of the CLB product.

The commercial alternative licensed product is available from Immuno and therefore will not be available FOC. RG to write to previous users (ie clinicians) of the CLB product outlining the proposed change of supplier, the reason for the change and indicating that in the interests of user convenience/cost efficiency, SNBTS West will hold a small stock of the Immuno product and will cross charge when supplied. (Precedents for cross charging already exist eg with Porcine Factor VIII (NERTC) and recombinant Factor VIII (ERTC). **RG**

RG will e-mail her proposed letter to users to RTDs for comments **RG**

prior to issue.

98.3 4.5 LEGAL POSITION ON BLOOD GROUP LABELLING OF COMPONENTS

4.5.1 MSC believed that in terms of the Consumer Protection Act, SNBTS were liable for the correct labelling of blood components. MB to draft a letter to CLO to confirm this understanding(via AMD). **MB**

4.5.2 This item had been stimulated by interest in the use of the Computer Crossmatch. MSC agreed in principle that SNBTS should be proactive on this issue and invited RG to bring forward some proposals for discussion. **RG**

98.3 4.6 PCR SAMPLE ARCHIVE

4.6.1 MSC discussed D32/98 and a revised version tabled by BD (doc ref D40/98). BD/MB agreed to convert this document into an SOP. **BD/MB**

4.6.2 MSC recommended that local (RTC) archives should continue to be collected until 31 December 1998.

98.3 4.7 CMV SERONEGATIVES: LEUCODEPLETION

It was noted that this issue would be discussed at the forthcoming SACTTI meeting. A copy of the briefing note prepared by Dr L Williamson for that discussion was tabled at the MSC (ref D41/98). It was agreed that no action would be taken until the SACTTI meeting had taken place.

98.3 4.8 COMMUNICATION OF SNBTS POLICY OUTWITH SNBTS

4.8.1 Correspondence between IMF and Dr A Robinson (NBA) was tabled at the meeting (ref D42/98). MSC agreed that SNBTS policies normally should be approved by SNBTS Board before being communicated outwith the organisation. Exceptions would be dealt with on a case by case basis.
MB to arrange to send copies of approved SNBTS policies to Dr A Robinson and Dr T Napier (Welsh BTS). **MB**

4.8.2 MSC asked MB to consider releasing SNBTS policies as controlled documents - MB agreed to consider this but advised that this would generate additional work. **MB**

98.3	5	PES

98.3 5.1 JF joined MSC for this item and the Committee suggested potential starting dates for various developments and nominated individuals with whom JF could liaise to firm up details, including costs. A few additional items were added.

98.3 5.2 The revised listing of developments/nominated individuals is as shown in appendix 2.

98.3	6	SNBTS ANTI-D PROGRAMME

98.3 6.1 MSC acknowledged the efforts which had been made to produce D35/98 and welcomed the helpful data it provided.

98.3 6.2 On the basis of D35/98, and against the expectations of the CSM announcement,expected on 30 March 1998, MSC agreed that the temporary discontinuation of donor boosting would continue. However, the position would be kept under careful review.

98.3	7	SOURCING OF NON-UK PLASMA FOR FRACTIONATION

98.3 7.1 A position paper on the above, prepared by MB, was circulated prior to the MSC (D43/98 for reference).
BC tabled two summary papers, one assessing quality issues relating to different plasma sources, the other providing comparative donor epidemiology. Slight modifications were made at the MSC and the revised versions are included with the minutes as D44/98.

98.3 7.2 MSC restated the SNBTS commitment to use plasma from voluntary non-remunerated donors but recognised the over-riding responsibility to maintain supply of licensed products for use in NHSiS.

98.3 7.3 Against the background set out above, the following points were raised:

7.3.1 MCA have indicated they may require SNBTS to change their packaging to indicate whether a product is derived from UK/non-UK plasma.

7.3.2 Re non-UK plasma, PFC plan to crush and fractionate pools from different suppliers separately, then combine to produce finished product.

7.3.3 The validity of the comparison of epidemiological data was questioned since US uses test kits that are generally one generation behind UK.

7.3.4 There is a potential risk of pools having a greater viral load.

7.3.5 It was noted that there is a need to develop a process for determining at which point epidemiological risks of imported plasma are considered to be unacceptably greater than that of plasma from Scottish donors.

7.3.6 There is a theoretical risk of introducing new agents/viruses not currently tested for through using non-UK plasma - eg 'Gulf War Syndrome'.

7.3.7 There is a risk to continuity of supply of finished product and an associated risk of needing to 'juggle' with limited supplies of raw material.

7.3.8 Risk of CJD recall under FDA criteria; MCA have indicated there will be no UK recall if a US donor develops classic CJD (as opposed to nvCJD) although there would be a recall in the US. It will be difficult to manage any publicity arising from this.

7.3.9 Unknown status of US quality systems - eg extent and performance of computerised systems; use of 'assumed negative' release; donor deferral registries etc.

7.3.10 QPP seems very well organised - eg full medical of donors including screening new donors for narcotics; quarantine of plasma until three satisfactory donations have been given; 60 day quarantine hold period etc.

98.3 8 AOCB

98.3 8.1 Methylene Blue Treated FFP

8.1.1 CVP advised MSC that the 01 May 1998 start date should be moved to 01 June 1998 (delayed availability of packs plus light boxes).

8.1.2 Dr A Todd has prepared a patient information sheet and CVP is preparing a prescriber information sheet. These were particularly important in the absence of the planned BCSH guideline publication.

8.1.3 CVP advised that BMcC had delayed issuing his communication to Consultant Haematologists which was aimed at establishing MBT FFP demand - eg for TTP; HUS etc. CVP has this and will issue 24/27 April 1998. **CVP**

8.1.4 MB to revise the SNBTS policy on this issue before the end of May 1998. **MB**

98.3 8.2 FUTURE AGENDA ITEMS

The following were raised as future agenda items:

- the use of whole blood (vs red cells and discarding plasma);
- professional consultation within SNBTS on Strategy;
- MBT FFP specification.

98.3 9 DATE, TIME, PLACE OF FUTURE MEETINGS

The following dates have been established for routine MSC meetings:

- Tuesday 02 June 1998
- Tuesday 01 September 1998
- Tuesday 01 December 1998

All meetings will be in the SNBTS Board Room, commencing 10.30