MEETING OF THE SNBTS MEDICAL AND SCIENTIFIC COMMITTEE
10 OCTOBER 1995
CONFERENCE ROOM, SNBTS HQ

MINUTES

95.3.1 **PRESENT**

Prof J D Cash (Chair)	JDC
Mr M Bruce (Secy)	MB
Dr E Brookes	EB
Dr G Galea	GG
Dr J Gillon (Item 95.3.4.4)	JG
Dr D F Hopkins (In attendance)	DFH
Mr C Jowsey (Item 95.3.4.2)	CJ
Dr A Keel (Items 95.3.4.1-4.4 & 4.6)	AK
Dr D B L McClelland	DBLMcC
Dr M McClelland	MMcC
Dr J McMenamin (Item 95.3.4.7)	JMcM
Ms J Pelly (Item 95.3.4.1)	JP
Dr R J Perry	RJP
Dr C V Prowse	CVP
Dr M Peterkin (for WRTC)	MP
Dr S J Urbaniak	SJU

The meeting started at 10.30 and finished at 17.35.

95.3.2 **MINUTES OF 17 MAY 1995 MEETING**

Corrections to these minutes (issued with the agenda) were approved and the revised minute was considered to be a true record of the 17 May 1995 meeting.

95.3.3 **ACTION CHART UPDATE**

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

95.3.4 **TOPICS FOR DISCUSSION**

1. **IMPROVING CARE FOR SCOTTISH PATIENTS WITH PRIMARY HYPOGAMMAGLOBULINANEMIA**

   i. JP introduced paper D21/95 which had been approved by Dr Kaminski as project leader and had the support of all 4 Scottish Consultant Immunologists. The following points were raised in discussion.

ii. EB was seeking reassurances that the proposals had been preceded by adequate consultation and it was suggested she contact Dr Kaminski. EB

iii. The subject of funding generated much discussion, particularly with respect to funding beyond the planned 2 year start-up phase. There were concerns that if funded by SNBTS, the project should be managerially accountable to the SNBTS. The subject of funding beyond the start up (2 year) phase also was seen as potentially problematic.

It was agreed that as project leader, Dr Kaminski should be made aware of MSC concerns and should be invited to make a presentation to available MSC members prior to an appropriate Board meeting. Proposals on how, when and by whom the Health Economics evaluation would be undertaken should be addressed in this presentation. JDC

iv. AK expressed concern that a declared objective of the project was to protect the SNBTS' commercial position". AK also expressed concern that the health economics evaluation was not being performed before a decision was taken to start the project.

v. The MSC thanked JP for her efforts to date and she left the meeting at 11.20am.

2. **SNBTS: GP NETWORKING AND STRATEGIC REVIEW PROCESS**

The MSC described a number of areas in which the SNBTS was actively networking with GPs eg

i. GG described "donor related"activities ie the SNBTS had sent GPs a mailshot giving useful information on the SNBTS, including contact details and publicity posters; a booklet was being prepared for GPs on medical deferral criteria; there is regular contact in respect of microbiology positive donors.

ii. SJU advised that information on donor deferral had been sent to GPs in their Region and that Grampian Healthboard is actively exploring transfer of activities from tertiary to primary healthcare eg community based transfusion, home therapy for primary hypogammaglobulinanemia.

iii. MP advised that some GP's in West Region had been enquiring about West RTC doing a wider selection of tests from a single sample eg rubella status on a sample referred for routine ante natal screening.

iv. All regions ensure GPs have a stock of SNBTS specific immunoglobulins.

v. It was suggested that GPs could be involved in "recruiting" suitable hyperimmune donors (eg Zoster).

vi. Following discussion of item 95.3.4.12 ii. it was agreed that Gps would be contacted to request them to check the immune status of at risk patients before administration of anti-VZ.

vii. MSC members agreed to forward any additional illustrations of interactions with GPs to Chris Jowsey. — ALL

3. PERSONAL INTERVIEW OF DONORS

i. GG described the present position ie anticipated release of funding at the end of this financial year would allow all centres to be implementing round about September 1996. It was agreed that this was a welcome improvement over the previous scenario where West RTC would have implemented this policy considerably later than other RTCs.

ii. GG advised that the Donor Consultants Group had discussed the matter of evaluating the efficacy of this policy and concluded that such evaluation would be too costly and long term to be pursued. Notwithstanding this view the MSC agreed that there was a need to generate prevalence data to demonstrate the policy was worth pursuing.

iii. DBLMcC agreed that SERTC would begin the process of collecting prevalence data on donors who had: — DBLMcC

- not been interviewed
- been interviewed and accepted
- been interviewed and deferred

Other RTCs would contribute to this process in due course.

It was agreed that this study would not delay the planned implementation of Personal Interviewing of Donors.

iv. It was agreed that funding for the Personal Donor Interviewing project would be prioritised with competing bids for available revenue moneys.

4. **HCV LOOKBACK**

i. **Update of SNBTS Position**

In preparation for a meeting of the MSBT ad hoc Working Party on HCV Lookback (13 Oct 95), AK had compiled a status report on the present SNBTS position and agreed to send this to MB for circulation to MSC. — AK/MB

ii. JDC was asked to write to enquire whether MSBT would wish to give SNBTS any clearer guidance on HCV lookback for recipients of IVIg. — JDC

iii. JG tabled a paper which for reference purposes has been given the identifier D35/95. This was considered by MSC and the results of these deliberations are recorded in iv and v below.

iv. With respect to recipients of blood components pre HCV testing, the MSC agreed:

- that testing of available donor archive samples would be neither cost effective nor appropriate
- that an offer to test anyone who had received blood components or products prior to HCV screening was likely to be the most effective option
- that this (latter option) should not be pursued until the present HCV lookback exercise was substantively complete
- that the sample collection and testing process should be provided by the Blood Transfusion Services

v. JG/AK were asked to present this view to the ad hoc Working party. JDC to communicate the SNBTS position to Dr Metters.

vi. **Defix**

It was agreed that in the context of HCV lookback, patients who had received Defix (or other prothrombin complex products) for warfarin reversal were an important group but would be very difficult to identify.

Inadequacy of blood bank records was thought likely to be problematic. However, DBLMcC advised that SERTC have already researched this problem (but taken no further action) back to 1973 and will brief JG on the difficulties encountered.

It was agreed that this group of patients would be included in the "catch-all" described at iv above.

5. **SNBTS PROPOSALS ON PARVOVIRUS B19**

i. CVP now has data on seroprevalence in younger age groups and will circulate this. — CVP

ii. The MSC approved the proposals contained in doc D25/95 and asked CVP to discuss these with JG before the SNBTS proposals are submitted to SACTTI. — CVP

iii. With respect to the symposium on parvovirus B19, CVP advised that Vox had requested the meeting report be submitted in the form of a review. This had now been accepted for publication - CVP would make copies available on request. — CVP

6. CJD

i. The lack of international consensus on CJD was discussed and RJP advised that CPMP is likely to extend the current Council of Europe guidelines to include deferral for a history of transplant of dura mater or cornea.

ii. The next revision of the Red Book will include deferral if the donor volunteers a family history of CJD.

iii. There is no UK policy on whether recall/lookback is necessary in respect of CJD. Presently, FDA require recall but the CPMP Biotech Working Party consider it is not appropriate to recall.

iv. It was noted that the SAC on donor selection has referred the matter of CJD to SACTTI and MSBT for consideration. In the meantime it was agreed that the SNBTS would take no further action until advised by MSBT.

7. **SURVEILLANCE AND REPORTING OF TRANSFUSION RELATION INFECTIONS**

i. The MSC agreed that the principles outlined in the NBA document D27.1/95 should be adopted by SNBTS who would communicate the relevant information to SCIEH.

ii. It was agreed that an SNBTS/SCIEH working party be appointed to develop the various systems and documentation. SNBTS representatives would include Jack Gillon plus another Donor Consultant and a member of the NITU team. JDC to communicate with JG. — JDC

iii. It was agreed that the Working Group would be invited to bring forward an implementation plan, including procedures, worksheets and policy on ownership of data/publications, to the next MSC (09 Jan 1996). — JDC

iv. JDC to communicate the SNBTS position to Prof Dan Reid, copy to AK. JDC also to advise Angela Robinson. — JDC

v. It was agreed that present reporting arrangements will remain in place until the new system is introduced.

vi. Jim McMenamin presented data from a paper tabled at the meeting (ref D36/95). It was of particular interest that the calculated incidence of HIV 'window" period donations (using various models) was 10 times the incidence observed by the SNBTS.

It also was noted that of the 60 HIV positive donors detected by SNBTS, 9 were not on the SCIEH database. JMcM to follow this up. — JMcM

vii. It was agreed that any publications which arose from the work undertaken to date would seen by MSC members before publication. — JMcM

8. REPORTING SERIOUS HAZARDS OF TRANSFUSION (SHOT)

i. DBLMcC advised that it was the SHOT Group's intention to have the reporting scheme in place by 1 April 1996.

ii. The SHOT reporting system would require participants who were reporting a suspected transfusion transmitted infection to make a simultaneous and urgent report to their supplier (ie BTC).

iii. Lack of funding for the scheme is currently a major obstacle. RCPath have declined to offer financial support but other possibilities were being pursued.

iv. The MSC gave their strongest possible support to this project and if required/appropriate would be prepared to recommend that SNBTS contributes a proportion of the funding.

9. PCR TESTING

RJP explained the current position.

Following transmission of HCV by a batch of Baxter intramuscular immunoglobulin (Gamma guard), the FDA introduced a requirement that all such products which had not been subjected to a viral inactivation process should be tested prior to release for HCV RNA by PCR.

It was anticipated that CPMP will adopt this policy, which will affect PFC's specific immunoglobulin products, possibly by 1 Jan 1996.

MB agreed to discuss the establishment of a project team with Bruce Cuthbertson. MB

10. MALARIA ANTIBODY DONATION TESTING

GG informed colleagues that following an apparently satisfactory evaluation, the malaria antibody test kits were not reacting satisfactory with control materials. It was noted that the matter was on the agenda for the forthcoming SACTTI meeting.

11. MICROBIOLOGY SCREENING: REACTIVE RATES

The MSC confirmed that only % reactive rates should be divulged to commercial companies.

12. ZOSTER Ig

i. The MSC approved the proposals made in document D32.1/95 and asked for an update report in 6 months. — CVP

ii. The MSC accepted Karen Bell's proposals concerning prescribing practices for Zoster Ig. It was agreed that RTCs would pursue implementation. It was also agreed that the most appropriate vehicle for communicating this would be via SCIEH. JDC to write to Dr Goldberg, copy to Jim McMenamin. — JDC

iii. It was noted that the changes outlined in D32.3/95 have been implemented.

13. RECOMBINANT FACTOR VIII UPDATE

The MSC noted the latest projections. The key messages were that plasma targets will not be reduced for next year and if the 'driver" becomes IVIgG, will change very little for the foreseeable future.

14. EC RESOLUTION ON BLOOD SAFETY AND SELF SUFFICIENCY IN THE COMMUNITY

The MSC considered that the SNBTS is making good progress towards securing the objectives of the resolution.

95.3.5 ITEMS FOR NOTING

1. ANTI-D PLASMA TARGETS

i. SJU advised that Centres are not presently meeting targets and that boosting will be necessary.

ii. RJP advised that PFC had been supplying anti-D to the British Pregnancy Advisory Service (because of supply problems with BPL). Katherine Reid had recently visited BPAS to discuss supply (6000 x 250IU/annum) and was told that patients in England were being refused termination's because of lack of anti-D.

iii. SJU explained that he had not been aware that the SNBTS was supplying BPAS with anti-D and asked to be kept informed of such issues in future. — RJP

iv. MP agreed to find out about the BPAS office/activity in Glasgow and report back. — MP

2. SACTTI

JDC advised that he would be seeking to ensure minutes/agendas for SACTTI meetings were circulated to the MSC. This was welcomed by colleagues. — JDC

95.3.6 AGENDA PLANNING

An updated agenda plan is provided as appendix 2.

95.3.7 AOB

1. DONOR SELECTION

Jack Gillon had communicated some concerns about the imminent changes to donor HIV selection criteria. The MSC felt unable to support JG's position.

2. PCR: TESTING OF BOOSTER CELLS

The MSC supported Eddie Follett's proposal that testing of a sample collected at least 12 months after the donation is frozen is not appropriate for "booster" red cell donors.

3. HCV FALSE POSITIVES: REINSTATEMENT

Having previously approved outline proposals made on this subject by Eddie Follett, the MSC approved the formal submission on re-instatement.

4. SNBTS GUIDELINES FOR THE IMMUNISATION OF HUMAN VOLUNTEERS FOR ANTI-D PRODUCTION

SJU circulated a draft revision of the above guidelines. Comments to be submitted to SJU by end of November. — ALL

5. MANAGEMENT ARRANGEMENTS MRU

DBLMcC expressed concern at the apparent lack of communication concerning the management arrangements for MRU following Eddie Follet's departure and requested that JDC and D McI meet with the Operational Directors to brief them.

6. MSBT: FFP QUARANTINE

RJP offered to send MB a copy of the last MSBT minute covering this issue. — RJP

7. MAC: ANTI-D IMMUNISATION PROGRAMME

DBLMcC advised that MAC would be undertaking further work in this area.

95.3.8 DATE, TIME & PLACE OF FUTURE MEETINGS

09 January 1996, 10.30am Conference Room, HQ
23 April 1996, 10.30am Conference Room, HQ
09 July 1996, 10.30am Conference Room, HQ
24 September 1996, 10.30am Conference Room, HQ
10 December 1996, 10.30am Conference Room, HQ

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