

**"RED BOOK"
UKBTS/NIBSC EXECUTIVE COMMITTEE
WEST MIDLANDS BLOOD CENTRE
WEDNESDAY 9 OCTOBER 1996**

28 OCT 1996

MINUTES OF THE EIGHTH MEETING

EXEC8.1	PRESENT	Dr P Flanagan (Chair items 2-6) Dr W Wagstaff (Chair items 7-13) Mr M Bruce Prof J D Cash Dr M Ferguson Dr V James Dr P Phillips Dr R Warwick	PF WW MB JDC MF VJ PP RW
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APOLOGIES: were received from Dr T Barrowcliffe; Dr M Kavanagh; Dr E Love; Dr D B L McClelland; Dr A Robinson; Dr G Schild; Dr M de Silva.

MB was representing DBLMcC and was invited to function as Secretary for the meeting.

EXEC8.2 **RE PUBLICATION OF 3RD EDITION**

PF advised WW had now identified a publisher who will produce the 3rd edition at a price that is substantially lower than HMSO (Price £2.90 per copy). WW intends to have the copies produced and made available to Blood Centres and hospitals in the UK. Cost recovery from sales external to these sources would part-fund the publication. It was envisaged that BTS would administer the distribution process and create a database of recipients of the 3rd edition to facilitate the process of issuing updates. Distribution would be complete within the current financial year.

The Executive Committee endorsed this proposal.

EXEC8.3 **DECLARATION OF INTERESTS**

The Executive Committee noted that SACs were approaching this matter independently and agreed that a generic system was desirable. It was noted that a useful article dealing with this issue had recently been published in the BMJ.

It was agreed that SAC Chairs who had developed (or were developing) a system for recording the interests of SAC members would send details to WW. WW would propose a generic approach for the next Executive Committee meeting.

SAC Chairs/WW

EXEC8.4

UK-WIDE REPRESENTATION

The Executive Committee acknowledged that the minutes from several SACs did not reflect the fact that the business of the meetings were being conducted on behalf of the UK Blood Transfusion Services.

It was agreed that WW should bring this to the attention of all SAC Chairs (and through them to the Committee Members).

WW

EXEC8.5

SAC ON DONOR SELECTION

EXEC8.5.1

COMMUNICATION WITH DONOR CONSULTANTS

VJ advised the Executive Committee that in July 96 the SAC had organised a meeting that was open to all UKBTS donor consultants. This had proved very successful and would be repeated on a six monthly basis. The next such meeting was scheduled for Feb 97.

EXEC8.5.2

DONOR DECLARATION

VJ described progress made regarding the donor declaration (which will replace NBTS 110). The declaration focuses on the donor's understanding of what is on the form and is based on the wording currently used by NLBTC and SNBTS. Once the final version is available it will be:

- added to the revised MAD guidelines
- incorporated into the Pulse system

It was noted that G Galea/M Thornton were taking this matter forward in SNBTS.

This initiative was unanimously supported by the Executive Committee.

EXEC8.5.3 POST DONATION ILLNESS

VJ advised that Dr T Wallington was chairing a subgroup to develop guidance on Post Donation Illness.

The subgroup had not yet reported but would be identifying conditions that were significant in this respect.

Final proposals would be agreed with QPs (at PFC and BPL) before including in revised MAD guidelines.

VJ

EXEC8.5.4 CJD

VJ advised that direct questioning had been implemented from August this year. Data was not yet available for the UK as a whole, however to date 3 donors have been identified and excluded in Southampton and Oxford. The Executive Committee noted that RTC's had not been told to advise fractionators if a donor had been excluded on this basis. Clarification on this requirement was being sought, the Executive Committee accepted that this policy would remain in place until the views of the fractionators was clear. It was noted that a review meeting would take place in February 1997.

EXEC8.5.5 FACE TO FACE INTERVIEWS

MB asked whether the last SAC minute, which indicated that face to face interviews were "obligatory and in line with minimum standards", was accurate. VJ indicated this was not the case ie there was a recommendation to UKBTSS to consider implementation.

VJ agreed to revise the SAC minutes accordingly.

VJ

The Executive Committee felt WW should emphasise the need for careful use of language when formally recording SAC decisions and actions.

WW

EXEC8.6 **SAC ON TRANSFUSION TRANSMITTED INFECTIONS**

EXEC8.6.1 **MALARIA ANTIBODY TESTING**

PF advised that Dr J Barbara will be updating SACTTI on progress with this matter. PP noted that an American review of transfusion associated malaria had demonstrated that most deaths related to infection with non-falciparum strains. PF acknowledged this and identified that the issue of cross reactivity with non-falciparum strains had been addressed in the sensitivity evaluation by Dr P Chiodini. The key outstanding issue that needs to be addressed before SACTTI can make a formal recommendation concerning this assay is the reproducibility between Blood Centre laboratories and Reference Centres. If this can be achieved PF considered that this assay would permit significant operational gains to be achieved without reduction in quality or safety.

EXEC8.6.2 **CJD**

EXEC8.6.2.1 PF advised that a series of meetings on CJD had taken place, the most recent of which was at NLBTC and was chaired by Prof Pattison (Chair of SEAC).

Prof Pattison had provided an update on progress into the investigations of prions, with particular emphasis on the variant form of CJD.

EXEC8.6.2.2 The Executive Committee noted that SACTTI would be preparing a paper for MSBT (cc Prof Pattison) setting out the concerns of the UKBTS with regard to CJD, the lack of relevant experimental data and the approach required to generate the required information.

PF offered to circulate the current version of this paper to interested Executive Committee Members. Members to contact PF directly. It was noted that the paper would be updated following a meeting of SACTTI on 04 Nov 96.

ALL

EXEC8.6.3 **HTLV**

EXEC8.6.3.1 PF confirmed that the SACTTI proposals on introducing some form of screening donors for anti-HTLV was presently under consideration. **It was noted that an additional consultative step, involving the NHS Executive, had now been introduced and that a decision on screening would be announced in due course.**

EXEC8.6.3.2 PF advised that following discussion between B McClelland and A Robinson a Strategic Group had been set up to consider the implications of a possible requirement to implement the anti-HTLV screening. The following have been achieved/noted:

- the need to evaluate test kits - this was well in hand with Leeds co-ordinating the preparation of 2000 aliquots for distribution to UKRTCs to evaluate assay specificity
- Drs B Dow and E Follett from SNBTS MRU had access to these samples
- the provision of an interim "go/no go" standard had been discussed with NIBSC (Harvey Holmes)
- Dr J Barbara was developing evaluation and confirmatory testing protocols. Drs B Dow/E Follett will be evaluating the performance of confirmatory assays
- the requirement for consistent approaches to confirmatory testing was acknowledged. Professor R Tedder had emphasised a requirement for this to include molecular based viral detection.

The Executive Committee unanimously endorsed the proposal that the evaluation of equipment/kits for anti-HTLV screening should proceed on a UK basis.

EXEC8.6.4 FRESH FROZEN PLASMA ETC

EXEC8.6.4.1 Against the expectation that Octapharma would soon have an MCA licence to provide virally inactivated plasma (Octaplas) in the UK, PF set out UKBTS actions to date.

EXEC8.6.4.2 A review meeting of invited experts had taken place at RCPATH, London on 10 Sept 96. A key action was concerned with devising a strategy to educate users as to the appropriate use of FFP (60% is used inappropriately) and the relative merits of conventional FFP vs VIP. Good progress had been made and a second meeting was scheduled for 15 Oct 96.

EXEC8.6.4.3 PF advised that he had prepared a dossier on the viral safety of FFP and offered to make copies available on request.

Members to contact PF for a copy if interested.

ALL

EXEC8.6.4.4 MB asked whether the statement that [FFP and Cryo] "were no longer produced from first time donors" had ever been confirmed ie it appeared the policy had been issued but was not clear if implementation had not been confirmed. This provoked lively discussion on a principle which merits further consideration.

EXEC8.6.4.5 PF advised he was discussing the cost/benefit/risk analysis of conventional FFP vs VIP and Methylene Blue (MeBI) treated FFP with a Public Health Economist.

EXEC8.6.4.6 Baxter had told NBS they will have a number of MeBI boxes available for evaluation this year but PF feels that a validated system for the production of MeBI treated FFP is some way off.

EXEC8.6.4.7 **There was consensus that the provision of an unpooled plasma component was the most desirable option.**

EXEC8.6.4.8 **It was considered that with respect to FFP, the relative risk of minipool testing by PCR, in conjunction with the use of "accredited" donors, was well worth pursuing for selected patient groups.**

EXEC8.7 **ISBT 128**

EXEC8.7.1 WW introduced this topic and provided some perspective to the virtual inevitability of the UKBTS adopting Code 128.

EXEC8.7.2 A proposal from SACIT detailing how the UKBTS could best proceed with ISBT 128 was tabled by WW (doc EC46/96).

The Executive Committee discussed the SACIT proposals. Whilst there was general support it was felt the proposals needed to be amplified to provide:

- **greater clarity**
- **more detailed budgetary requirements (upper limit with key items identified)**
- **the key role to be played in the project by hospital staff**
- **a realistic report date (April 97 was not considered realistic)**

WW to communicate this to Dr Love.

WW

EXEC8.7.3 Once the Executive Committee were satisfied with the revised proposal they would submit requests to National Authorities for pro rata funding.

EXEC8.8 **SAC ON BLOOD COMPONENTS**

EXEC8.8.1 **COMMITTEE MEMBERSHIP**

MB advised that at a meeting at Lancaster on 9 Sept 96, the membership considered that since they had fulfilled their present remit, they should offer their resignation. Those who wished to offer their services for the new committee had done so.

There was some discussion on the future Chairmanship of this SAC. It was agreed this would be considered outwith the meeting and that WW would tactfully establish the availability of a suitable replacement for Brian McClelland, taking account of the potential impact on other SACs, notably SACTTI.

WWW/ALL

EXEC8.8.2 **EVALUATION OF NEW COMPONENTS**

EXEC8.8.2.1 **The Executive Committee agreed there should be a UK approach to the evaluation of new/novel blood components and that such activity should be under the auspices of the SAC on Blood Components ie either approved or commissioned by the SACBC and reporting to that SAC.**

EXEC8.9 **SAC ON TISSUE BANKING**

Present ad hoc arrangements would continue until a formalised position was established.

EXEC8.9.1 RW explained the SAC and subcommittee structure and activities for Tissue Banking ie SAC members represented on subgroups, BATB actively involved.

EXEC8.9.2 The combined efforts of SAC and subgroups have resulted in considerable progress being made towards developing a Red Book Section on Tissue Banking.

Chapter 1 of this section will deal with "General Considerations on Tissue Donor Selection".

Chapter 2 will deal with the entire process from tissue retrieval to issue and includes bone, valves and skin.

RW indicated that the current versions would benefit from further consultation eg from SACTTI members, and indicated that she intended circulating current drafts to PF and to members of the Executive Committee for comment. RW

EXEC8.9.3 **It was agreed the SAC on Tissue Banking should not attempt to have this section available for publication with the remainder of the 3rd edition. It was agreed there was much merit in issuing a separate Guideline text on Tissue Banking.**

EXEC8.9.4 RW advised that a special SACTTI had been arranged for April 1997 to consider virological aspects of Tissue Banking. A leading American Red Cross tissue banker (Ted Eastland) would be visiting the UK at that time and would make a major contribution to the planned discussions. Topics to be addressed include:

what tests and test kits; the significance of haemodilution (of donor re sample provided for testing); PCR testing; counselling etc

EXEC8.9.5 **The Executive Committee noted that BATB had been actively involved or consulted in the production of the Red Book section on Tissue Banking but were concerned to hear that many UK Tissue Banks (ex BTS) will not be able to meet the guidelines drafted by this SAC.**

EXEC8.9.6 **The Executive Committee asked RW to pass their congratulations to the SAC and subgroups for the substantial progress made in a relatively short period.** RW

EXEC8.10 **SAC ON PLASMA FOR FRACTIONATION**

The Executive Committee considered that there was a need for the above SAC to be reactivated to more effectively service the requirements of other SACs eg this Executive meeting had discussed issues of relevance to (and requiring interaction with) SACs on Donor Selection and Transfusion Transmitted Infections.

It was considered the changing emphasis for this SAC may be better served if the Chair was actively involved in the fractionation process. WW to discuss with Dr T Barrowcliffe and determine the best way forward. WW

EXEC8.11 **SAC ON REAGENTS**

There was no report from the above SAC.

EXEC8.12 **STATUTORY POSITION OF THE GUIDELINES**

EXEC8.12.1 The Executive Committee noted with interest the successful legal challenge in the US by a private citizen vs the AABB, who were found negligent in terms of failing to set appropriate standards for surrogate marker testing.

EXEC8.12.2.1 WW indicated that the progression towards transferring responsibility for standard setting in Transfusion Medicine from the Council of Europe to the European Parliament was inexorable and will, of necessity, change the rules under which the entire "Red Book" organisation functions.

EXEC8.12.2.2 **It was agreed there was a need to develop operating mechanisms that would ensure effective collaboration between national competent authorities and professional groups. It was judged that this matter was of sufficient importance to merit separate consideration at a specifically arranged meeting of the Executive Committee with representatives from National Authorities.**

WW

EXEC8.12.3 **WW proposed that the notion of a Red Book Secretariat should be developed within the Framework of 12.2.2. This was agreed. It was noted that NIBSC had already given a commitment to part fund this activity. Distribution of guidelines/updates would be included within the remit.**

EXEC8.13 The Chairman noted that as Prof J D Cash would be retiring in Dec 1996, this would be his last meeting of the Executive. The Executive Committee wished to record their sincere appreciation for the substantial contribution JDC had made to initiating the Red Book and serving on its various Advisory and Executive Committees. The Committee offered JDC their congratulations and warmest wishes for his impending retirement.