**Minutes of the 13th Meeting of the**
**UKBTS /NIBSC EXECUTIVE COMMITTEE**
**Held at the Kings Fund on 1st April 1999**

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**Present:** **ACTION**

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| Chitra Bharucha | CB |
| Frank Boulton | FB |
| Martin Bruce (Representing Lorna Williamson) | MB |
| Morag Ferguson | MF |
| Henry Hambley | HH |
| Virge James (Chair) | VJ |
| Elizabeth Love | EL |
| Cristina Navarette (Representing Mahes DeSilva) | CN |
| Geoffrey Schild | GS |
| Terry Snape | TS |

1. **Apologies:-**

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|---|---|
| Mike Kavanagh | MK |
| Maurice McClelland | MM |
| Peter Phillips | PP |
| Angela Robinson | AR |
| Mahes DeSilva | MS |
| Ruth Warwick | RW |
| Lorna Williamson | LW |

2. **Minutes of the Meeting : 14th December 1998**
Following ratification of the minutes by the Chairman there were some further corrections as follows:-

Page 1.
Spelling of Chitra Bharucha

Page 2. Section 4 :
Should read "Tissue Banking document: The medical assessment of donors of tissues (MAD-T)". This had been circulated, no comments received and it has now been issued as a controlled document by Doug McDougal.

Page 5. 4th Paragraph, Line 1
"RW raised the question whether" (delete expressed the view as all)

Last line to follow the last sentence: -
"She expressed that in tissue banking there was a small mass of expertise and that each SAC needs a critical mass to enable learning. For Tissue Banking new blood would be need to be recruited....."

Page 9, SACTB third paragraph

Delete "there may even be a need for a different Red Book for tissues". RW disagrees strongly with this statement.

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| **3.** | **Matters Arising** | **Action** |
| **3.1** | In the absence of AR the outcome of discussions with Stephen | **outstanding** |
| **3.1** | Janisch regarding BCSH recommendations was not known. | **AR** |
| **3.2** | **Handbook of Transfusion Medicine** | |
| | Actions still outstanding | **VJ** |
| **3.3** | **Page 6. Special SAC Meetings** | |
| | CB said that there will a special SACTTI meeting which will address future testing issues. The date to be confirmed to chairs of SAC's. | **CB** |
| **3.4** | **Page 6 - Other SAC Minutes.** | |
| | It was agreed that SAC Minutes should be circulated to Medical Directors and other SAC chairs emphasising that the information given is professional advice. | **Chairs of SAC's** |
| **3.5** | **Revised terms of reference EC01/99** | |
| | VJ tabled her document on Revised Terms of Reference. A possible new name for the liaison committee was discussed and the preferred option was "UKBTS / NIBSC a Joint Standards Committee. | |
| | Regarding the initial draft terms of reference there had been feedback from the SACBC (EC 201999) Regarding comment 6 this is not the remit of the Red Book Committee and should be taken into account by medical doctors. Regarding comment 7 SAC's are free to consult wherever they wish and various feed back mechanisms already exist. | **VJ then Chairs of SAC's** |
| | VJ will re-issue EC01/99 for distribution to SAC's by SAC Chairs. | |
| **4.** | **Amendments/Changes to 3rd Edition of Red Book** | |
| | These are currently undergoing document control. The next (4th) version of the Red Book should be re-written for November 99 for publication in 2000. Chairs of SAC's should review their chapters. | **Chairs of SAC's** |
| **5.** | **Red Book on the Intranet/Internet - Printable/Non Printable?** | |
| | The original printing of the Red Book has cost £10,000. and 1,000 copies have been printed. 800 are distributed free and some are | |

sold at £35. per copy and 100 remain unsold. VJ has asked the Royal Society of Medicine to quote for future publication. Currently a part time secretary does the typing and Andrew Lowe acts as the in-house publisher. The RSM already produce practice guidelines and is used to handling controlled documents. The Red Book is currently on the NBS Intranet but not the Internet although there is great enthusiasm for this from the NBS IT team. It was agreed that printed and Internet versions were desirable. For the Internet version it was suggested that names should be removed. There would be no financial implications as the NBS already has a website at Colindale. There was further discussion about producing the Red Book on individual websites e.g. NIBSC, Wales, SNBTS and discussion on whether the NIBSC could be the parent website. There was support for this idea and GS will contact his head of Informatics at NIBSC (Monica Jordan) to discuss this further. In due course MAD and MAD-T Guidelines would also need to be on the Internet. Regarding separate SACIT Guidelines which will in future be incorporated in the Red Book, these could also be included on the Internet.

**GS to contact Monica Jordan**

**EL to check re SACIT standard**

**7. Red Book Organisation Involvement in Europe**

VJ tabled a paper on relevant organisations (no document number). Further additions to that list were discussed and GS agreed to produce a glossary of terminology.

**GS**

EL expressed concern that there is no UK involvement on the committee which considers EDI standards (CEN TC 251/WG1/PT32)
EL to send information to VJ.

**EL/VJ**

**ALL**

It was also agreed to list various ISBT organisations and any UK representation.

**8. SAC on Fractionation**

Following the list the meetined this with MK and Bruce Cuthbertson. It was agreed that it would be difficult to produce a meaningful document under the current circumstances but an attempt will be made to produce a revision of the common specification for plasma fractionation. The SACBC expressed the view that the Plasma Fractionation Group should continue to meet in order to keep other organisations up to date. CB also expressed this view and suggested that a representative Fom the SAC on care and selection of donors should attend the meetings. FB will discuss this with the SAC on care and selection of donors and liaise with TS. It may also be appropriate to have a link with the SABC but the key link was felt to be with the SAC on care and

**FB/TF**

selection of donors.

At this point there was further discussion on EC02/99 page 2 produced by the SACBC. This had recommended merger of the SACBC and the Immunoglobulin Working Party. TS explained that the Immunoglobulin Working Party had not met for three years and the last issue discussed was the protocol for immunisation of donors, which is no longer appropriate. Matters discussed prior to this were mainly operational. GS felt that there may be some technical matters which need to be discussed but this could be done within the existing Plasma Fraction Group. The Ig Working Party previously worked independently and not via the SACBC as originally intended. It had several functional relationships (donors/infection/plasma fractionation/patients). There was much discussion on:-

a) Whether this group should exist
b) Where it fits in

The latter being dependent on what is under discussion.

VJ agreed to discuss the matter with Stan Urbaniak,who previously chaired the Working Party, and report back. **VJ**

Also arising from EC02/99 it was confirmed that the Working Party on Peripheral Blood Stem Cells which had considered donor matters had completed its work. The Working Party on Haemopoetic Progenitor Cells, chaired by Derwood Panphilon, feeds back to the SACTB and draft guidelines are in progress. VJ will clarify the relationships between these two groups. **VJ**

*Note added after meeting: The WP reports to the SACTB where there is additional expertise on some areas of haematopoietic stem cells especially cord blood and bone marrow donations and general GMP expertise in non-blood issues. The WP document will therefore be reviewed by the SACTB prior to furhter consultation beyond the WP and SAC. It is intended that a further Red Book section will result. It is pertinant to note that the WP has representation from the British Society for Bone Marrow Transplantation and follows the ISHAGE/EBMT document widely accepted by bone marrow transplanters in the US and Europe*

**9. New SAC on HLA and Platelets**

CN answered questions on this matter. The current SAC on reagents in immuno haematology has a HLA sub committee and now needs to consider platelets and granulocytes. The proposal is that the SAC be renamed as the SAC on Immuno haematology with two sub groups reporting to it:-

a) Red Cell Automation
b) HLA Platelets/Granulocytes

CN said that the UK TSSA will shortly cease all laboratory activities and this particularly affects the HLA field. This has been discussed with the BHSI and a meeting will be held shortly to examine the impact. It was noted that the NIBSC is also in discussion with the UKTSSA.

There are clearly a number of interlinking groups whose role and relationships need to be clarified and the membership of the SAC on Immuno haematology and its sub groups will be reviewed. VJ will reply to AR, MS and Mike Murphy. **VJ**

**10. SAC on Blood Components**

**10.1 Comments and Proposals EC02/99 Page 2**

See above. Also comments were noted regarding the Apheresis Working party. This currently reports to the SAC on Care of Donors but has obvious links with the SACBC. It was agreed that this needs to be a permanent working group. It was noted that the NBS Apheresis Technical Group is separate from the Apheresis Working Group and exists to implement policies. It was felt that a UKBTS Technical Working Group would be more appropriate. Along the same lines the SACBC acknowledged the value of the NBS Leucodepletion Science and Quality Group and would like it to continue as a sub group of the SACBC, probably with wider representation to assist on technical matters in the future.

VJ will write to the National Medical Directors with these proposals. **VJ**

**10.2 Methylene Blue FFP EC17/99**

This paper was tabled by MB who explained the background. Although there are concerns that the European Pharmacopoeia does not describe methylene blue, the MCA has indicated that there is no reason why the SNBTS should not continue to issue this product. It was felt that there was a need to produce a draft specification for the "Red Book" (EC16/99)

The reduction in Factor 8 yield is noted and it was suggested that the specification for Faction 8 yield should be 0.45 at which level 95% of units are within specification. Data on the treatment of neonates is being collected. It was noted that the NIBTS has started issuing MBFFP for neonates. It is not clear what should be monitored in these patients. CB expressed caution about including a specification in the Red Book for the time being and suggested

that this be reserved for the fourth edition to be published in the year 2000 giving more time to observe progress with this product. However, there is no need to preclude the use of MBFFP and in order to gather more date on neonates, every centre which has been supplied with MBFFP for neonates would be asked for clinical feedback. This possibility has already been discussed with Brenda Gibson (BSH/BCSH). It is suspected that the PEI (Paul Ehrlich Institute) will recommend removal of Methylene Blue by filtration.

**10.3 Proposals for changes to Blood Bag Base Label (Re: ISBT 128) EC03/99**

The SACIT had asked the SACBC to discuss proposals for changes to the base label because of the need to be more restrictive in the text. MB said that some legal advice was required regarding the wording and the outcome would be taken back to the SACBC and SACIT. **MB**

**10.5 Identification of Sickle Positive Donors, EC04/99**

Universal leucodepletion had thrown up the problem of filter blockage/unsatisfactory results when filtering red cells from sickle trait donors. It was recommended that the SAC for the Care and Selection of Donors should be asked to consider the problem and make some proposals. Although FB had some reservations that this SAC was not the most appropriate, he agreed to examine the issue. **FB**

**10.6. Re-issue of Blood Components**

No papers were supplied for this item. MB said that there was a need for a protocol to allow units to be returned from hospitals. However, the requirements are very stringent and the number of units likely to be returned low and it may therefore not be worthwhile to pursue although it would be valuable to have a protocol for use where return is deemed to be unavoidable. FB expressed concern and said that he would prefer to recommend that hospitals should improve their practices to avoid wastage. TS said that this issue was a quality system matter and not the remit of the SAC's or the Executive. Wording in the Red Book may need to be changed.

**11. SAC on Care and Selection of Donors**

**11.1 Minutes of Meeting - 24th June 1998 EC05/99**

**11.2 Special Meeting - Re: Revision of Safety of Blood Leaflet 24th June 1998 - EC06/99**

**11.3 Second Special Meeting: Re Revision of Safety of Blood Leaflet 15th December 1998 - EC07/99**

**11.4 Donor Care Meeting - 20th October 1998- EC08/99**

**11.5 Minutes of Meeting - 22nd February 1998 -EC09/99**

The above papers had been previously circulated. FB discussed the main issues which had involved the SAC on care and selection of donors recently.

**MAD Guidelines 1999 (version 007).**
These should be ready for distribution by 19th July 1999. One major change is regarding T Cruzii as it is agreed that the currently identified risk criteria are irrelevant. Much more relevant is the residency/birth/transfusion history in South America. The MAD Guidelines will be produced and printed in electronic format.

- **Safety of Blood Leaflet** - There has been two meetings of experts. There will probably be no major changes but some rewording. VJ said that it would be desirable to take evidence for decisions made by the SAC to the next Council of Europe meeting in order to try to influence a sensible decision in that meeting.

- CN asked where advise would be obtained regarding bone marrow and progenitor cell donors. This is the remit of the SACTB.

**12. Standing Advisory Committee on Information Technology**

**12.1 Minutes of Meeting Held on 11th February 1999- EC10/99**

EL discussed current items of importance to the SACIT

- **Tissue Banking codes** - There is a need to develop tissue codes and the current ABC Codabar is no longer suitable. So far the ISBT Working Party on Automation and Processing has not developed ISBT 128 tissue codes. Advice is awaited from the ICCBBA but in the meantime EL is arranging a meeting of a sub committee to develop tissue codes and it is quite possible that the U.K. will lead the way on this issue.

- **ISBT 128 Implementation Planning** - EL explained that a sub committee is currently developing a working standard of the ISBT 128 application specification. When complete this will be circulated to a variety of individuals for comment and

will then be passed to the Red Book Executive. Following this, the sub committee will work on guidelines for implementation. The SACIT is quite clear that its remit does not extend to implementation but has emphasised the need for implementation to be on a UK wide basis.

- **EDI Issues** - The SACIT recognises the need to establish links with the NHS Information Management Groups. There is concern that no individuals from the UK have been involved in the European group working on EDI (CEN TC251/WGI/PT32) EL has brought this to the attention of the NBS in the past. EL to supply VJ with further information. **EL**

GS asked whether it would be appropriate for Monica Jordan from the NIBSC to join the SACIT. EL explained that the SACIT is already a large committee with at least four IT experts. However, this proposal will be discussed at the next SACIT meeting. **EL**

**13. Standing Advisory Committee on Reagents for Immuno haematology**

**13.1 Minutes of Meeting Held on 16th February 1999 EC11/99**
No comments in the absence of MS

**14. Standing Advisory Committee on Tissue Banking**
No comments in the absence of RW

**15. Standing Advisory Committee on Transfusion Transmitted Infections**

**15.1 Minutes of Meeting - 24th November 1998 EC12/99**
**Minutes of Meeting - 19th January 1999 EC13/99**
**Minutes of Meeting - 9th March 1999 EC14/99**

CB summarised the main items occupying SACTTI time.

- **The management of jaundiced history donors SACTTI 02/99**. This flow chart was prepared by Richard Tedder and was considered to be sound and endorsed by the SACTTI. The Executive recommended acceptance of this algorithm for donors who give a history of jaundice and this will be incorporated into MAD007.

- **Live and Cadaver Donors** - It was noted that the SACTTI had recommended that the same standard should apply to both

- **Risk Assessment Report** - This has now been published and a

number of issues relating to TSE's have been raised. These will be discussed at the May meeting of the SACTTI and a position statement developed. **CB**

**MB asked what is the mechanism for making proposals regarding acceptance of tests through the MDD -** This was raised in relation to Malaria. The problem with Malaria testing has been the absence of a control until recently and the availability now of a control has highlighted problems with the Launch test. MB said the only batches of the Launch test to be released will be ones which pass the control and those that do so, do not compare as favourably as the index kits used by the SNBTS. CB will ascertain the mechanisms for adding items to the MDD list. **CB** GS noted that the NIBSC now needs to take more seriously the development of reference materials for malaria. **GS**

- It was noted that CB had written to the JCVI regarding indications for the use of immunoglobulin.

**16. Items raised by NIBSC**

**16.1 New British Working Standards**

Second Anti HCV Standard developed
HBV RNA Working Standards developed
First HBV DNA International Standard and
First HIV RNA International Standard expected October 1999

Further work on genomic detection of HAV and B19 to be conducted. Material is currently available for reference.

**16.2 There is interest in detecting HBV by genomic amplification** because of a problem with mutant strains in the USA and failure to pick these up in serological tests. TS said that a significant proportion were missed because of the inadequate sensitivity levels of approved test kits.

**16.3 SOGAT (Standardisation of a Gene Amplification Method)**

Next meeting 7th May 1999

**16.4 TSE's**

NIBSC will strengthen its activities in this area and establish a TSE reagent project. The priority will be materials useful for standardising future tests/infectivity standards/monoclonal antibodies. Funding is being sought but the WHO has also asked for the project to be set up.

**16.5 Tissue Banking Liaison**

This group exists at the NIBSC and Ruth Warwick attends the group.

**16.6 New Laboratory at NIBSC**

The DOH has provided funding for a new laboratory for biological reference materials to be commissioned by 2001.

**17. Any other business**

**17.1 Future of NAT Steering Group and its link to the Red Book**

This was briefly discussed. EL indicated that there is still a great deal of work to be done to be done on the NAT project and therefore a need for the NAT Steering Group to continue. In due course when all phases of the project have been fully implemented this will become a purely operational issue with guidance on testing provided by the SACTTI.

**18. Date of Next Meeting**

Wednesday June 30th 1999 - BJ to notify of venue
Tuesday October 5th 1999 - NIBSC to be confirmed.