

# Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 22<sup>nd</sup> Meeting held at the West End Donor Centre, London  
on Thursday 21<sup>st</sup> February 2002

Meeting commenced at 11.00 am

## PRESENT

Mr Paul Ashford	<b>(PA)</b>	- Standing Advisory Committee on Information Technology
Dr Frank Boulton	<b>(FB)</b>	- Standing Advisory Committee on Care and Selection of Donors
Mr Martin Bruce	<b>(MB)</b>	- Standing Advisory Committee on Blood Components (Attending for Dr Lorna Williamson)
Dr George Galea	<b>(GG)</b>	- Standing Advisory Committee on Tissue Banking
Prof. Ian Franklin	<b>(IF)</b>	- Medical Director, Scottish National Blood Transfusion Service
Dr Virge James	<b>(VJ)</b>	- Chair, JPAC
Dr Mike Kavanagh	<b>(MK)</b>	- Medicines Control Agency
Dr Liz Love	<b>(LL)</b>	- Standing Advisory Committee on Transfusion Transmitted Infection
Dr Brian McClelland	<b>(BM)</b>	- Standing Advisory Committee on Clinical Transfusion Medicine
Dr Morris McClelland	<b>(MM)</b>	- Medical Director, Northern Ireland Blood Transfusion Service
Dr Morag Ferguson	<b>(MF)</b>	- National Institute of Biological Standards and Control
Prof. Stan Urbaniak	<b>(SU)</b>	- Standing Advisory Committee on Immunohaematology

## IN ATTENDANCE

Miss Caroline J Smith **(CJS)** - Secretary

Virge James welcomed Martin Bruce to the Group who was attending for the SACBC and Stan Urbaniak attending his first meeting as chair of the SAC on Immunohaematology.

### 1. **APOLOGIES**

Apologies were received from:

Dr Bruce Cuthbertson	<b>(BC)</b>	- Standing Advisory Committee on Plasma for Fractionation
Dr Stephen Inglis	<b>(SI)</b>	- Director, National Institute of Biological Standards and Control
Dr Peter Phillips	<b>(PP)</b>	- National Institute of Biological Standards and Control
Dr Angela Robinson	<b>(AER)</b>	- Medical Director, National Blood Service
Dr Lorna Williamson	<b>(LW)</b>	- Standing Advisory Committee on Blood Components
Dr Keith Wilson	<b>(KW)</b>	- Acting Medical Director, Welsh Blood Service

### 2. **MINUTES OF 21<sup>ST</sup> MEETING HELD ON 11<sup>TH</sup> OCTOBER 2001**

**ACTION**

2.1. The minutes were accepted and approved with the following amendment.

#### **Ethics Committee - item 6.3.**

Correct spelling Stephen Janisch.

### 3. **MATTERS ARISING**

**ACTION**

3.1. **Membership of SACs - item 3.4.**

Membership lists of some SACs have still not been received. Chairs, who had not already done so, were asked to send details of their membership, names and addresses to VJ. This is urgent.

ALL

3.2. **Clarification on indemnity - item 3.5.**

VJ had circulated Mr Stephen Janisch's letter, JPAC Enc. 02/01.

Martin Bruce asked whether there would be problems for members who were not employed by the Blood Services.

FB requested information about lay members. At the moment there are none, VJ to check with Stephen Janisch about lay non-professional members.

VJ

LL asked VJ if we could circulate the Stephen Janisch letter to members? There was no objection. VJ will write to all members as suggested in the letter.

VJ

3.3. **Labelling for patient notes - item 3.6.**

FB informed the JPAC he is taking this matter to the BCSH Transfusion Task Force meeting in March, Chaired by Jenny Duguid.

FB

3.4. **CoE draft "Guide on Safety and Quality Assurance for Organs, Tissues and Cells" - item 3.7.**

Copy of the formal response to the CoE document, for the "Red Book" archives had been received.

Closed

3.5. **Membership of SAC on Information Technology - item 3.10.**

Nick Tandy was joining the SAC. Someone with a blood component background would also be invited.

3.6. **Ethics Committee - item 3.13 and 6.3.**

To be discussed when Ian Franklin arrives.

3.7. **New section on platelets - item 4.2.3.**

SU informed JPAC that he accepts the wording of this section. VJ will circulate the new section to JPAC for approval. When approval is received this new section will appear on the website.

VJ

3.8. **Proof reading - Item 4.2.3.**

VJ had written to SAC chairs regarding editing/proof reading of future editions of the Red Book in November 2001. VJ informed JPAC that she will budget for the extra £3,000 to have the document in "Word" format for the 7<sup>th</sup> edition.

Post meeting note

**ACTION**

*An electronic version of the 5<sup>th</sup> Edition has been received in "rtf" format and circulated to all SAC Chairs.*

3.9. **DSG and T-DSG restrictions - item 4.3.4.**

JPAC felt that relevant professionals should have access, always bearing in mind that the aim is to give general public access in a few years.

3.10. **Proposed project on donor selection criteria - item 6.1.**

On the agenda.

3.11. **Ethics committee constitution - item 6.3.**

AER was asking for advice from Jennie Gubbins etc.....  
Still awaiting.

3.12. **Consultant in Transfusion Medicine - SAC - item 9.2.**

Job description circulated to JPAC.

**Closed**

3.13. **Membership of the SAC on Plasma for Fractionation - item 13.**

BC has asked Andrew Watson to join this SAC.

3.14. **T-DSG distribution outside the Services - item 14.2.**

It is acknowledged that T-DSG should be available to all Tissue Bankers, whether within or outwith the Blood Transfusion Services.

3.15. **Approval of T-DSG by JPAC - item 14.2.**

The T-DSG was circulated to JPAC, has been approved and appears on the website.

**Closed**

3.16. **Malaria and gamma irradiation - item 14.3.**

GG has informed Tim Wyatt as requested.

**Closed**

3.17. **Problems with e-mails between NBS & SNBTS - item 15.3.**

Ongoing.

3.18. **Forward Looks from SAC Chair - item 17.1.**

VJ asked chairs, who had not already done so, to send their forward looks as soon as possible.

**Ian Franklin and Brian McClelland arrived 11.25.**

4. **"RED BOOK" ADMINISTRATION**

**ACTION**

4.1. **Red Book Administration Report by Virge James - JPAC Enc. 02/02**

VJ quickly went through this report for the group.

4.1.1. Access to DSG and T-DSG on the website

A meeting has been scheduled on 6<sup>th</sup> March with Serge Six, David Hutton, Virge James and Nicky Anderson to discuss the details of ensuring that up to date documents are on the website, and also accessible to the NBS National Contact Centre. It is important to ensure that these are the unique base documents on these matters.

5. **“RED BOOK” 5<sup>TH</sup> EDITION**

Implementation dates have now been received from 2 of the 4 Services.

Post Meeting Note

*Northern Ireland implementation date still awaited*

6. **REPORT FROM UK FORUM MEETING HELD ON 1<sup>ST</sup> FEBRUARY 2002**

IF reported back from the UK Forum meeting.

- ♦ EU Directive on Tissues - Peter Doyle is the contact at the DoH.
- ♦ VJ has talked to Angus Macmillan Douglas and the UK Forum has accepted the Terms of Reference for the SACCS D.
- ♦ The JPAC website has been very well received.
- ♦ VJ will be attending the UK Forum meeting in Belfast on 3<sup>rd</sup> May 2002.

6.1. GG raised the issue of 'surplus' tissues. The concern is whether the UK should be providing surplus tissues to other Countries.

LL to ask RW if the NBS has stopped exporting tissues on the grounds of unknown vCJD risk. LL

Should SACTTI/SACTSC consider this issue? – Chair of SACTSC to pose suitable question to Chair of SACTTI. GG

7. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS**

7.1. The draft remit from the Sub-Committee on Apheresis is to be discussed at the next SACBC meeting. Lorna Williamson also asked to look at the relationship with the NBS Technical Sub-committee (reporting to both the SACCS D and SACBC).

7.2. **BSI Technical Committee**

**ACTION**

The BSI Technical Committee have never met. It is understood that they may be considering standards for blood bags, collapsible containers, giving sets, compatibility.

JPAC approved the new representative for UK BTS - Mark Nightingale QA Manager at Southampton.

7.3. **Forward Looks**

MB to e-mail forward looks to VJ.

**MB**

17<sup>th</sup> May 2002 a meeting is planned on granulocytes - JPAC will be invited.

7.4. **In vitro diagnostics Medical Devices Directive**

MB to forward to SU any information with regard to CE marking of reagents. MF stated that this was also an issue for NIBSC.

We will have to meet the requirements of the Directive.

All SACs should be aware of how this Directive impacts on their work.

LL to ensure that the Working Party on Parasitology and Blood Safety (NBS) are aware.

**LL**

MB would furnish LL with appropriate question for the sub-group to consider.

**MB**

8. **STANDING ADVISORY COMMITTEE ON THE CARE AND SELECTION OF DONORS**

8.1. **The possible impact of testing for vCJD on the UK blood supply - JPAC Enc. 02/04**

FB went through the report for the group. This is a first response and a lot more work needs to be done. We are working on the assumption that the suggested changes will be permanent, not temporary measures in case of emergencies.

**JPAC Comments**

The paper was well received and JPAC thanked the SAC for the work and careful thought that had gone into producing this paper. The following feedback was noted:

8.1.1. **Title**

The title should be changed to indicate that this is ongoing, constantly reviewed work.

8.1.2. **Frequency of donation**

The Services should continue to encourage, by all available means, 3 times yearly attendance.

8.1.3. **Genetic Haemochromatosis**

**ACTION**

The implementation strategies are for the Services now that SACCS and JPAC have approved the "principles".

8.1.4. Donor Age

Accepting older donors should be based on evidence that they come to no harm.  
May also be a matter for EU Directive in which case we will not be able to change.

8.1.5. 'Tropical' Donors

Much depends on the robustness of the MAT test.

8.1.6. Medications

Details to be worked out.

8.1.7. Body Piercings

Need to discuss with SACTTI.

8.1.8. Anaemia Tests

Results awaited.

8.1.9. Past History of Malignancy

Need to gather worldwide views.

8.1.10. Men who have sex with men

Remain unchanged.

FB was asked to continue with the work, prioritising the conditions which would decrease donor losses.

The paper to be circulated to other SACs for their input and awareness.

**Conclusion**

1. No immediate changes.
2. VJ to present summary to UK Forum in May indicating that the work is in progress.

8.2. **David Hutton**

FB informed the JPAC that David Hutton had been post for since October 2001 and will be based at the WBS from June 2002.

VJ to encourage David Hutton to attend donor sessions to keep up practical skills.

**VJ**

8.3. **Membership of SACCS D**

**ACTION**

FB would like to invite Henry Hambley to join the SACCS D. JPAC agreed.

8.4. **Adverse Events of Donation**

The importance lay in uniformity in recording and reporting adverse events. Definitions of such events need to be agreed.

It was suggested that the word "Surveillance" appear in the title.

VJ

## 9. **STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE**

### 9.1. **Notes for UKBTS/NIBSC JPAC - JPAC Enc. 02/15**

BM tabled and went through these notes for the group.

### 9.2. **Handbook of Transfusion Medicine**

Brain McClelland will produce a short statement about the official standing of the Handbook of Transfusion Medicine (as printed version), BCSH guidelines and web version of the Handbook of Transfusion Medicine.

BM

FB to send list of BCSH members to Caroline Smith.

FB

## 10. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

### 10.1. **Structure of SAC on Immunohaematology**

As the structure is very large SU proposes restructuring the SAC and sub-committees. Paul Metcalf will act as NIBSC link for the Platelet Immunology Group.

There needs to be major revisions of the relevant sections relating to reagents and the IVD directive. It is too soon to have this done for the 6<sup>th</sup> Edition of the "Red Book".

### 10.2. **Proposed Working Parties**

SU proposes three Working Parties with definite remits and time scales, specifically to provide the revision.

#### 10.2.1. **1<sup>st</sup> Working Party on In-vitro Diagnostics Medical Devices Directive**

Proposed Chair of the Working Party John Allen.

SU read out a draft remit. JPAC approved the remit VJ asked SU to email remit to Caroline Smith.

#### 10.2.2. **2<sup>nd</sup> Working Party - Review of Donation Testing**

**ACTION**

Proposed chair of the Working Party John Kirkwood.

Look at aspects of donation testing which lack clarity. Invite members from each of the Services. SU to check with Martin Bruce.

#### 10.2.3. **3<sup>rd</sup> Working Party - Patient Testing**

SU asked for clarification as to whether patient testing falls within the remit of the "Red Book". SU to ask Geoff Poole to write to FB, as secretary of BCSH Task Force, so there is an item on the agenda of the BCSH meeting on 14.3.02. The expertise of the Reference Laboratories lies within the BTSs and therefore it is felt that certainly reference testing is part of the "Red Book".

10.3. **Examples of Active Issues**

What should be the level of anti-A and Anti-B and evidence for HLA antibody screening?

MF informed JPAC that NIBSC has been asked to look at list of Haematology standards currently available.

11. **STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY**

11.1. **ISBT128**

UK Forum asked the SAC on IT to look further into what is required and produce a timetable.

Europe role is gaining momentum - Germany and France going to ISBT 128 in the future.

ISBT 128 on the way to providing a Europe wide structure. ICCBBA now publishing documents.

PA has had input into progenitor cell documents. GG to take to Derwood Pamphilon through SAC on TSC.

**GG**

11.2. **Electronic messaging**

SAC on IT asked to produce a suitable mechanism. HL7 will be adopted by the NHS in the UK.

EDI Task Group needs to become a sub-committee of SACIT. PA to produce a remit. Remit will have to go to the UK Forum.

**PA**

11.3. **Information transfer using barcoding**

Guidance is required on how to read barcodes. PA to write to FB to put on BCSH meeting agenda.

**PA**

11.4. **Non UK plasma**

**ACTION**

Imported plasma (FFP) will need to be re-labelled and the risk of this needs to be assessed.

IF - is it possible to quantitate the risk of re-labelling? Is this a significant risk? ?MSBT and DoH to be informed.

A risk assessment needs to be carried out and the information passed to MSBT. This is an "implementation" issue and in the first instance the Services should be

**VJ**



made aware.

**12. STANDING ADVISORY COMMITTEE ON PLASMA FOR FRACTIONATION**

VJ informed the JPAC that BC is reviewing the chapter.

**13. STANDING ADVISORY COMMITTEE ON TISSUES AND STEM CELLS**

**13.1. CJD and Tissues**

GG informed JPAC that risk assessments for bone have been sent to EOR. The plan is to raise the issue again in the next few months.

**13.2. Donors exposed to artificial skin - non viable**

Issue has been resolved - risk quite low.

**13.3. Donors who have suffered from depression**

Proposal from Andrew Tullo - Chair of UKT Sub-committee on Corneas.

It was felt that the proposed questions were unspecific and would exclude many unaffected donors.

SACCSD also felt that the questions were non-specific and therefore it was inappropriate to ask.

No further action envisaged. GG to write to Dr Tullo

**GG**

**Martin Bruce left the meeting at 14.30.**

**13.4. vCJD**

The CJD incident panel advice has been commented on. However, GG noted that for tissues it states that "Advice on exposure will be available at a later date". GG to email BM to see whether MSBT are considering this.

**GG**

What will happen if CJD is found to be transmissible via processed bone? Currently orthopaedic surgeons seemed oblivious to any problems.

SAC to draft a questionnaire to be sent to orthopaedic surgeons explaining the proposals. Also contacting professional associations involved.

**GG**

**13.5. Draft EU Directive on Tissue Banking**

**ACTION**

2 meetings have taken place. Deirdre Feily has attended as an expert. Draft 3 is being prepared. It will be at least 2004 before it becomes law in the UK.

It would be better to work with UKT towards one common guideline for Tissues and Organs.

IF informed JPAC that this was discussed at last UK Forum. UK Forum is going to

invite the Chief Executive of UKT for a preliminary meeting to explore common issues.

13.6. **Update Chapters**

For next edition writing a rationale for guidelines. A Browser version of T-DSG is requested

VJ

14. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION**

14.1. **Membership of SACTTI**

Chris Hodson has been invited to join the SACTTI as the operational representative.

14.2. **vCJD Working Party**

2 meetings have taken place, 17<sup>th</sup> September 2001 and 1 February 2002, and the membership has been widened to include FB, BC and Phil Yates. The minutes will be circulated to JPAC through the SACTTI.

SACTTI want to extend the work of the TSE Working Party. It is important that issues should be channelled through SACTTI and to maintain this relationship.

14.3. **Joint meeting with the SACBC on Bacterial Contamination on 26 November 2001**

LL went through the draft minutes of this meeting.

14.4. **Hepatitis B Core**

Request to look at Hepatitis B Core testing also to include HBV DNA testing. LL to finalise at next SACTTI and pass through JPAC.

14.5. **Extension of NAT**

Producing a paper.

14.6. **New Chapter for "Red Book"**

SACTTI is working on a completely new chapter for the Red Book.

14.7. **Joint meeting with SACTSC**

**ACTION**

Joint meeting with SAC on Tissues and Stem Cells will take place in November 2002.

14.8. **Pathogen inactivated plasma**

SACTTI and SACBC should be aware of current manufacturers pressure to use their systems.

VJ

15. **ITEMS RAISED BY NIBSC**

No items were raised.

**16. REPORT FROM COE DRAFTING GROUP MEETING SEPTEMBER 2001 & COE SP-R-GS MEETING FEBRUARY 2002 BY VIRGE JAMES**

Congratulations to SACCSO on excellent paper on T.Cruzi.  
Malaria too complicated - back on agenda next year.  
Very close working between CoE and EU on the EU Directive on Blood. At the moment the Directive Annexes will only deal with issues related to patient safety and not donor safety.

**17. ANY OTHER BUSINESS**

**17.1. Mike Kavanagh**

MK informed JPAC that he would be leaving the MCA at the end of April 2002.  
VJ thank MK for his input over the years.

MK to talk to MCA about another representative for JPAC.

**18. DATE AND VENUE OF NEXT MEETING**

Thursday 13<sup>th</sup> June 2002 at Birmingham New Street.

**The meeting closed at 15.20**