

Joint UKBTS/NIBSC Professional Advisory Committee

**Minutes of the 23rd Meeting held at Birmingham New Street Conference Suite,
on Thursday 13th June 2002**

Meeting commenced at 11.00 am

PRESENT

Mr Paul Ashford	(PA)	- Standing Advisory Committee on Information Technology
Dr Frank Boulton	(FB)	- Standing Advisory Committee on Care and Selection of Donors
Dr Morag Ferguson	(MF)	- National Institute for Biological Standards and Control
Dr George Galea	(GG)	- Standing Advisory Committee on Tissues and Stem Cells
Prof. Ian Franklin	(IF)	- Medical Director, Scottish National Blood Transfusion Service
Dr Stephen Inglis	(SI)	- Director, National Institute for Biological Standards and Control
Dr Virge James	(VJ)	- Chair, Joint UKBTS/NIBSC Professional Advisory Committee
Dr Liz Love	(LL)	- Standing Advisory Committee on Transfusion Transmitted Infection
Dr Brian McClelland	(BM)	- Standing Advisory Committee on Clinical Transfusion Medicine
Dr Morris McClelland	(MM)	- Medical Director, Northern Ireland Blood Transfusion Service
Dr Tony Napier	(TN)	- Acting Medical Director, Welsh Blood Service
Dr Angela Robinson	(AER)	- Medical Director, National Blood Service
Mr Chris Rudge	(CR)	- Medical Director, UK Transplant
Prof. Stan Urbaniak	(SU)	- Standing Advisory Committee on Immunohaematology
Dr Lorna Williamson	(LW)	- Standing Advisory Committee on Blood Components

IN ATTENDANCE

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

For clarity these minutes follow the agenda order, not the order in which they were discussed at the meeting.

VJ welcomed Dr Stephen Inglis and Mr Chris Rudge to JPAC as new members.

1.

APOLOGIES

Action

 Dr Bruce Cuthbertson **(BC)** - Standing Advisory Committee on Plasma for Fractionation
 Mr Chris Turner **(CT)** - Medicines Control Agency

2.

MINUTES OF THE MEETING ON 21ST FEBRUARY 2002
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 The minutes of the last meeting held on 21st February 2002 were approved after the following corrections.
 - 2.1. **David Hutton - Item 8.2.**

 David Hutton has been in post since October 2001 and has been based at the WBS since June 2002.

- 2.2. **Handbook of Transfusion Medicine - Item 9.2.** **Action**
- Clarification of this minute: 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**
- 2.3. **Item 11.1.**
- Should read: "ICCBBA now publishing documents."
- 2.4. **Item 11.2.**
- Should read: "HL7 will be adopted by the NHS in the UK".
3. **MATTERS ARISING FROM THE MINUTES OF THE LAST MEETING**
- 3.1. **Membership of SACs – item 3.1.**
- The membership lists of the SACs have now been received.
- 3.2. **Lay non-professional members – item 3.2.**
- Awaiting reply from Mr Stephen Janisch.
- 3.3. **Indemnity – item 3.2.**
- Letter to be sent by VJ. **VJ**
- 3.4. **New section on platelets – item 3.7.**
- Platelet section approved by JPAC and will appear on the web site, as soon as possible. **VJ**
- 3.5. **Surplus tissues – item 6.1.**
- The concern is whether the UK should be providing surplus tissues to other Countries, in view of the vCJD risk.
- LL to put on agenda of the Joint SACTSC and SACTTI meeting in November 2002. **LL**
- 3.6. **Sub-Committee on Technical Aspects – item 7.1.**
- LW informed JPAC that the Sub-Committee of SACBC on Technical Aspects is chaired by Chris Prowse. The Terms of Reference of the Sub-Committee on Apheresis have been approved by SACBC and are now with the SACCSA. **FB**
- 3.7. **In vitro diagnostics Medical Devices Directive – item 7.4.**
- LL to ensure that the Working Party on Parasitology and Blood Safety is fully aware of this Directive. LL progressing. **LL**
- 3.8. **Non UK plasma – item 11.4.**
- The need to relabel imported FFP has been drawn to the attention of the Medical Directors for them to discuss with their respective Service implementation groups. **Medical Directors**

- 3.9. **Donors who have suffered from depression – item 13.3.** **Action**
- GG to clarify whether he or Ruth Warwick should write to Dr Andrew Tullo. **GG**
- 3.10. **vCJD – item 13.4.**
- 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 ask BM to see whether MSBT are considering this. **GG**
- SACTSC to draft a questionnaire to be sent to orthopaedic surgeons explaining the proposals. Also contacting professional associations involved. GG progressing. **GG**
- 3.11. **Browser version of T-DSG – item 13.6.**
- This was agreed. VJ to progress. **VJ**
4. **“RED BOOK” ADMINISTRATION**
- 4.1. **JPAC report to the UK Forum – JPAC Enc. 02/16**
- Following the UK Forum meeting of 3 May 2002, VJ requested that all SAC Chairs make sure they undertook the work outlined in their “Forward Looks” and were in a position to report back by the end of the year. It is also important that SAC Chairs receive reports from working parties and sub-committees, so that the work of JPAC remains cohesive and accountable. **ALL**
- VJ is finally in a position to start collecting the full JPAC archive material – prospectively and requests that she is added to the circulation lists of all standing advisory committees, sub-committees and working parties so as to get a full set of papers. **ALL**
- 4.2. **Attendance Registers**
- It was agreed that each SAC Chair would keep an attendance register for their SAC meetings and their sub-committees and working parties, as from now. **ALL**
- The JPAC Chair will keep an attendance register for the JPAC meetings. **CJS**
- 4.3. **Observers at JPAC**
- A request has been received from Prof. John Cash for an observer from the Irish Transfusion Service to attend JPAC meetings.
- A formal request should be made by the Chief Executive of the Irish Transfusion Service. VJ to write to Prof. John Cash. **VJ**
- 4.4. **New members of JPAC**
- Dr Stephen Inglis, Medical Director or NIBSC
Mr Chris Rudge, Medical Director of UK Transplant
Mr Chris Turner, Medicines Control Agency

5.	REQUESTS FROM THE UK FORUM	<u>Action</u>
5.1.	<p data-bbox="229 264 1118 293"><u>Professional view on pathogen inactivation of blood components</u></p> <p data-bbox="229 331 1297 421">UK Forum have requested a paper from SACBC/SACTTI on the professional view of pathogen inactivation of blood components and the evidence base for such procedures.</p> <p data-bbox="229 459 1238 517">LW requested a clear remit and stated that toxicological issues were outwith the expertise of JPAC.</p> <p data-bbox="229 555 1318 645">It was agreed that LW, BM and LL would produce a list of issues which JPAC felt they could comment on and VJ would forward this to the UK Forum to see whether this met the requirements of the UK Forum.</p>	LW, BM, LL & VJ
5.2.	<p data-bbox="229 683 911 712"><u>Review of Donor Selection Criteria and Processes</u></p> <p data-bbox="229 750 1193 779">The UK Forum requested an update on this task as soon as it was available.</p> <p data-bbox="229 817 847 846">FB stated that the most promising aspects were:</p> <ul data-bbox="229 846 536 936" style="list-style-type: none"> ◆ Extending age ◆ Medication ◆ Haemochromatosis <p data-bbox="229 974 1286 1003">VJ stated that we need to advance this issue for the UK Forum. VJ and FB to liaise</p>	VJ & FB
5.3.	<p data-bbox="229 1064 480 1093"><u>Red Book Budget</u></p> <p data-bbox="229 1131 1297 1256">VJ informed JPAC that we only have a small budget to cover meetings/speakers and that we have now started to receive a number of invoices for SAC meetings. She asked SAC Chairs to please try and hold meetings where the venues are free of charge i.e. West End Donor Centre or Birmingham New Street.</p> <p data-bbox="229 1294 1318 1352">IF stated that if this proved to be a problem VJ could ask the UK Forum to increase the budget.</p> <p data-bbox="229 1391 576 1420">VJ to monitor the situation.</p>	VJ
5.4.	<p data-bbox="229 1451 496 1480"><u>EU Blood Directive</u></p> <p data-bbox="229 1518 1011 1547">AER updated JPAC on the position of the EU Blood Directive.</p> <p data-bbox="229 1585 1238 1615">An EU Parliamentary amendment to Article 18a proposes the following wording:</p> <p data-bbox="229 1653 1318 1823">“A medical examination, comprising at least an interview and blood pressure check, shall be carried out before any donation of blood or blood components. The doctor shall be responsible, in particular, for giving donors the necessary information and gathering information from donors, and shall on the basis thereof, assess the eligibility of donors.”</p> <p data-bbox="229 1861 1254 1951">This wording obviously causes concern in the UK since we do not have medically qualified staff at all sessions, nor do we take blood pressure measurements on all donors prior to donation (discussed at SACCS in 1997/98). AER to clarify.</p>	AER

6. **RED BOOK 6TH EDITION** **Action**
- VJ reported that the 6th Edition was still on track for a publication date in November 2002.
7. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS**
- 7.1. **Retirement of the Chair of SACBC**
- LW announced her retirement as Chair of the SACBC after 6 years. VJ thanked LW for all her hard work as Chair of this very active SAC. LW agreed to hold the fort until a new chair is appointed.
- VJ to progress. VJ
- 7.2. **Joint SACBC/SACCS D meeting on Granulocytes (17th May 2002) – JPAC Enc. 02/30**
- LW went through the draft recommendations for JPAC, which were extensively discussed. Copies of the PowerPoint presentations from the meeting will be put together and circulated with the minutes of the meeting.
- Main issues
- (a) Exposure of donors to GCSF/starch/steroids
- Derwood Pamphilon document to go through SACCS D. FB
- (b) How to ensure that granulocytes are only issued where maximum benefit can be obtained.
- The suggestion was that a small panel of “experts” could be consulted every time this component was requested. LL stated that since there are agreed criteria for use of granulocytes to consult a panel every time would be laborious.
- General agreement was reached for the following procedure:
- Derwood Pamphilon to produce a list of accepted criteria and a list of 5 or 6 experts in the UK who would be available to all centres to discuss problems. When granulocytes are requested the Centre Consultant will act according to the criteria and, if the condition of the patient falls outwith the criteria, will consult with 1 or 2 of the named “experts”.
- IF suggested that a trial was needed to evaluate the effectiveness of the provided granulocytes.
- LW to take back to the group to redraft recommendations. LW
8. **STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**
- 8.1. **Patient Information Leaflet**
- This was issued for use from February 2002.
- AER stated that the leaflet was finally issued after 2 years of discussion and even so

we have been criticised for not consulting sufficiently. The SACCS D group to draft a short paper to be made available at sessions explaining our criteria.

Epidemiology data will be reviewed annually.

FB
FB & Kate
Solden

8.2. **Adverse Events of Donation Surveillance (AEDS)**

FB to report back to JPAC at next meeting.

FB

8.3. **SACCS D minutes of meeting held on 23rd January 2002**

Item 10. vCJD – Tissue Donation

A possible question for tissue donors/relatives: "Has the donor displayed any new symptoms in the previous 12 months which were sufficient for referral to either a neurologist and/or a psychiatrist?"

SACTSC and SACCS D to liaise through David Hutton and report to JPAC in October.
FB to progress.

FB

8.4. **Papers for SP-R-GS requested by VJ**

- ◆ CJD paper forthcoming.
- ◆ Malaria redraft forthcoming.

FB

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

9.1. **Handbook of Transfusion Medicine**

The SAC recognise a need for 1 or more consistent product(s).
There is a need for a generic pocket size version of the Handbook. The content needs to be brief, to the point and consistent with the Handbook and BCSH.

BM has developed a short questionnaire and letter getting the support of HTCs in using, distributing and reformatting the Handbook, which could go through National Transfusion Committees or Executive Groups. VJ agreed to send on behalf of JPAC.

VJ

AER pointed out that the Handbook needs to be in line with BBT2.

Post Meeting Note for information:

Health Service Circular HSC 2002/009 – Better Blood Transfusion Appropriate Use of Blood, issued on 4 July 2002.

9.2. **JPAC web site – JPAC Enc. 02/35**

BM tabled and went through Enc. 02/35 for JPAC.

The main issue is whether the JPAC site could carry a self-assessment programme based on the Handbook.

There was overall consensus that education was within the remit of JPAC.

SU stated that the BBTS Professional and Educational Committee are aware of the need and are meeting on Monday 17th June to discuss the issue. Members felt that close liaison was necessary together with evaluation of other sites offering such assessments.

The principle was accepted that providing educational material via JPAC was appropriate. More discussion needs to be held to decide most relevant manner and links. BM and VJ to progress.

BM & VJ

10. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

10.1. JPAC Enc. 02/29

SU drew the Committees attention to the following:

- Trevor Barrowcliffe will have a more formal relationship to the SAC.
- New list of standards – NIBSC standards produced by Susan Thorpe.
- An HLA standard in place by November.

10.2. **Working Parties**

Working Parties to consider specific issues have been set up and will report in due course.

1. Reagents IVDA
2. Donation testing

10.3. **Patient testing**

SU discussed the question of whether the Red Book should concern itself with patient testing. JPAC felt this was relevant, there needs however to be close liaison with BCSH.

Major revisions are expected for the 7th edition in 2004.

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

11.1. **SACIT Report to JPAC – JPAC Enc. 02/33**

PA went through this report for the group. The SACIT has 2 new members, Nick Tandy and Gordon Nicholson. Deirdre Fehily and Jonathan Wallis have both resigned from the SAC. An interested medically qualified person is needed on the group, not necessarily from within the Services. Names to be sent to PA.

All

11.2. **Proposal to establish SACIT EDI Task Group as a permanent Sub-Committee of SACIT – JPAC Enc. 02/32**

PA went through this paper with the group. There are still a number of areas where work needs to be done.

JPAC recommended that this group continue as a Working Party, but will keep the situation under review.

11.3. **ISBT 128 implementation**

A report had been submitted to the UK Forum. The SAC has been asked to propose a timetable for the completion of the full transfer to ISBT 128. Since it is a standard it is expected that the EU will drive this forward.

**Medical
Directors**

Medical Directors to discuss at UK Forum.

11.4. **BCSH Guidelines on Hospital Blood Bank Computing**

PA has written to the BCSH Transfusion Task Force regarding updating of the Blood Bank Computing Guidelines. No reply has yet been received. FB will follow up.

FB

New developments in blood bank computing practice are being introduced and the guidelines need to address these. One such example is a pilot project using RFID (Radio Frequency) tags that is being set up in Northern Ireland.

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

A revised Chapter will appear in the 6th Edition.

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

13.1. **“Red Book” 6th Edition – Part 5 Tissue Banking**

Chapter on progenitor cells – GG stated that 3 key issues regarding cord blood need resolving. These are:

- When should consent be obtained?
- Is a 6/12 post collection sample essential?
- Could untested cord blood be stored with tested cord blood in same container?

Agreement has not been reached on these issues within the SAC. These issues will be further discussed at a meeting in November, but in the meantime will be left out of the 6th Edition.

GG

GG to check the content of the current EU Directive for Tissues and Cells to see whether these issues are addressed.

GG

13.2. **Update from Chair of SACTSC – JPAC Enc. 02/20**

GG went through JPAC Enc. 02/20 for the group.

T-DSG – Entry on organ donation/transplantation

JPAC agrees that we should not accept organ recipients as donors of tissues.

Need to inform MSBT. GG to inform Peter Doyle with a copy to AER and BM.

GG

When MSBT have been informed VJ will issue under a concessionary letter and put a notice on the web site.

GG & VJ

13.3. **Keep Transplant Safe Leaflet**

GG informed JPAC that some of the wording was too explicit to ask relatives of cadaver donors.

JPAC agreed and accepted the new suggested wording: change “male to male sex” to

“any form of male homosexuality”.

Live donors of bone will be asked the same explicit questions that blood donors are asked.

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

LL informed the committee of the following main areas of current work.

14.1. **Bacterial contamination issues (resulting from the Joint SACBC/SACTTI meeting 26.11.01)**

These are under the leadership of Roger Eglin.

14.2. **Hep B Core Testing Paper**

Discussion document is still in draft form after 2 years, but will be available for the next JPAC meeting in October. Blood Services need to be informed early so that they are aware of possible implementation issues. Medical Directors to note.

**Medical
Directors**

14.3. **Papers in preparation by the SACTTI**

- Position paper on emerging pathogens
- Storage of archive samples
- Extension of NAT

There will be a joint SACTSC and SACTTI meeting on 12th November 2002.

14.4. **Working Party on vCJD**

The Working Party have already held 3 meetings and tackled some key issues. Papers are in preparation.

WHO is setting up a sub-group to deal with blood issues (Philip Minor and Trevor Barrowcliffe are members). It seems that further sub-groups will be set up and it is important that JPAC links in. LL to progress with AER and IF to UK Forum.

**LL, AER &
IF**

NOTE: JPAC Enc. 02/25 is draft.

14.5. **Working Party on Parasitology and Blood Safety**

LL went through JPAC Enc. 02/26 and 02/27 with the group.

This working party has advised on malaria and *T. cruzi* and Leishmaniasis. Malaria: VJ is expecting a revised paper to take to the CoE.

Dr Chris Whitty (Hospital of Tropical Diseases/London School of Hygiene and Tropical Medicine) to produce a recommendation.

Action for FB. This needs to come to JPAC for October 2002 so it can go to CoE for November 2002.

FB

The Working Party is now closed, but will be reconvened should new issues arise.

14.6. **Recommendation to re-define the UK Transfusion Microbiology Reference and**

Reporting Group as a permanent Sub-Committee of the SACTTI – JPAC Enc. 02/22 (SACTTI paper 02/26)

LL went through the recommendation. JPAC accepted the agreements and is willing for this group to become a permanent sub-committee of the SACTTI.

They currently report through Marcela Contreras in the NBS. The proposal is that the group reports both to DDR in the NBS and SACTTI.

VJ to write to Marcela Contreras.

VJ

15. JOINT MEETING OF THE SAC ON BLOOD COMPONENTS AND THE SAC ON TTI – 26TH NOVEMBER 2001 – JPAC Enc. 02/28

This paper was sent to the UK Forum in advance of full discussion at JPAC due to time pressures.

There has been a misunderstanding in that the target “implementation” dates, referred to in the paper, did not refer to implementation of the methods outlined, but to target dates for the setting up of the working groups and national programmes as suggested.

The UK Forum have asked JPAC that the paper be reconsidered and clarified. JPAC endorsed the recommendations and asked LL to represent the paper. It will then be sent to the UK Forum via the Medical Directors for the July meeting.

LL

Chris Rudge requested further information about HTLV testing .

LL

16. NIBSC

16.1. HTLV

NIBSC have a working standard.

16.2. CE Marking

The requirement that all reagents used outside the “legal entity” where they are produced require CE marking was reiterated.

16.3. Malaria

NIBSC is developing a NAT based detection method. Liaison with Roger Eglin was requested.

SI

17. ANY OTHER BUSINESS

17.1. “Red Book” 6th Edition – Blood Components

LW informed JPAC that the composition of the chapter will change and there will be summary tables as well in this edition.

17.2. European Haemovigilance Network (EHN) and SHOT

SHOT would like to participate in EHN. LL to progress with the UK Forum.

LL

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

Thursday 10th October 2002 at the West End Donor Centre in London