

# Joint UKBTS/NIBSC Professional Advisory Committee

## Minutes of the 29<sup>th</sup> Meeting held at Novartis Foundation, 41 Portland Place, London on Thursday 17<sup>th</sup> June 2004

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
Dr Bruce Cuthbertson	<b>(BC)</b>	-	Standing Advisory Committee on Plasma for Fractionation
Dr George Galea	<b>(GG)</b>	-	Standing Advisory Committee on Tissues and Stem Cells
Dr Richard Jones	<b>(RJ)</b>	-	Medical Director, Welsh Blood Service
Dr Liz Love	<b>(LL)</b>	-	Standing Advisory Committee on Transfusion Transmitted Infection
Dr Sheila MacLennan	<b>(SM)</b>	-	Standing Advisory Committee on Blood Components
Dr Brian McClelland	<b>(BMc)</b>	-	<b>Chair of JPAC</b> and the Standing Advisory Committee on Clinical Transfusion Medicine
Dr Morris McClelland	<b>(MM)</b>	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Willie Murphy	<b>(WM)</b>	-	National Medical Director, Irish Blood Transfusion Service
Prof. Stan Urbaniak	<b>(SU)</b>	-	Standing Advisory Committee on Immunohaematology
Miss Caroline J Smith	<b>(CJS)</b>	-	JPAC Office Manager ( <b>Secretary</b> )

For clarity items are minuted in the order they appeared on the agenda, not in the order discussed at the meeting.

### 1. **NEW MEMBERS OF JPAC**

BMc welcomed WM to his first meeting and announced that Ms Barbara Morris, from the Medicines and Healthcare Products Regulatory Agency, had accepted her invitation to join JPAC.

### 2. **APOLOGIES**

Dr Morag Ferguson	<b>(MF)</b>	-	National Institute for Biological Standards and Control
Prof. Ian Franklin	<b>(IF)</b>	-	Medical Director, Scottish National Blood Transfusion Service
Dr Stephen Inglis	<b>(SI)</b>	-	Director, National Institute for Biological Standards and Control
Ms Barbara Morris	<b>(BM)</b>	-	Medicines and Healthcare Products Regulatory Agency
Dr Angela Robinson	<b>(AER)</b>	-	Medical Director, National Blood Service
Mr Chris Rudge	<b>(CR)</b>	-	Medical Director, UK Transplant

### 3. **MINUTES OF THE MEETING ON 18<sup>TH</sup> FEBRUARY 2004**

The minutes of the last meeting were approved with the following amendments

- Item 4 delete “prefer to keep JPAC ..... linked.”
- Item 14 should read “... assessing the IV Directive is ongoing.”
- Item 15.2. should read “Working with Deirdre Fehily .....”
- Item 16. delete “AER informed JPAC ..... plasma”.
- Item 19.1. should read “110 Tissue Bank sites .....”.

### 4. **MATTERS ARISING NOT ON THE AGENDA (review of actions list)**

Only matters not on the agenda are minuted in this section.

#### 4.1. **Safety of Blood Leaflets – item 3.6.**

Inclusion of HTLV positive donors in deferral criteria - progressing.

FB

#### 4.2. **Liability – sending Tissues outside the UK – item 3.7.**

GG has written to AER regarding tissues and Derwood Pamphilon has also written regarding stem cells. Closed

#### 4.3. **Calculated Microbial Risk from Blood Transfusion – item 3.9.**

This was discussed again at the last SACTTI in May. SACTTI is preparing a paper and LL will bring this paper to the next JPAC meeting in November, after it has been signed off by the SACTTI.

LL

#### 4.4. **SACTTI Position Statement: CMV Seronegative vs leucodepleted blood components – item 3.10**

The SACTTI work is completed and this is on the agenda of the next BCSH meeting. Closed

#### 4.5. **Position Statement: NAT Testing – item 3.11.**

There are no proposals to amend this paper. Closed.

#### 4.6. **Website – Link to Blood Conservation Strategy – item 7.3.**

This will be pursued at the SNBTS/NBS Clinical meeting on 28<sup>th</sup> June 2004.

BMc

#### 4.7. **Proforma for the capture of donation and processing data for bacterially contaminated units – item 10.1.**

The Medical Directors have had this information and further actions rest with them. Closed.

MDs

#### 4.8. **Maximum storage time of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP – item 10.2.**

	<u>Action</u>
Concessionary letter was issued, on 24 <sup>th</sup> February 2004, extending shelf-life to 24 months.	
4.9. <b><u>Framework for evaluation of pathogen reduction of blood components - item 10.3.</u></b>	
SACBC & SACTTI will produce a “summary of issues” document for the UK Forum. This document will review and bring up to date the list of aspects being considered.	<b>SM &amp; LL</b>
4.10. <b><u>Database of evaluation in UK Blood Services for SACBC TG – item 10.5.</u></b>	
CJS to post on the website. Closed	<b>CJS</b>
4.11. <b><u>Leucodepletion residual risk – item 10.6.</u></b>	
SM is revising this paper including the levels of residual risk of CMV – in progress.	<b>SM</b>
4.12. <b><u>CoE “Guide to the safety and quality assurance for organs, tissues and cells” – item 11.2.</u></b>	
Copy received from Rachel Green and circulated to JPAC for information on 26 <sup>th</sup> February 2004.	
4.13. <b><u>Donor Selection Criteria – item 12.1.</u></b>	
The review of evidence base for current donor selection criteria was discussed at the last SACCS D meeting held in May and substantial progress has been made. FB will circulate these minutes to JPAC for information, even though they are still draft.	<b>FB</b>
4.14. <b><u>Autologous Labelling – item 15.1.</u></b>	
PA will send this document to CJS to circulate to JPAC. PA welcomed any comments on substance and asked that they be sent directly to him.	<b>PA, ALL &amp; CJS</b>
4.15. <b><u>Requirements to be met before reintroducing UK plasma – item 16.</u></b>	
JPAC agreed this was not an issue for discussion at this time.	
4.16. <b><u>I/v fibrinogen – contact at MHRA – item 19.2.</u></b>	
Chris Turner had suggested contacting Dr Joyce Lawrence at the MHRA. BMc will write to the MHRA with a copy to the MDs.	<b>BMc</b>
<b>5. <u>UK FORUM – JPAC Enc. 04/25</u></b>	
Morris McClelland went through his report (JPAC Enc. 04/25) for the group. CJS will circulate the JPAC Annual Report and BMc’s addendum.	<b>CJS</b>
<b>6. <u>JPAC ISSUES</u></b>	
6.1. <b><u>7<sup>th</sup> Edition of the Red Book</u></b>	
VJ started work on editing the 7 <sup>th</sup> Edition on 16 <sup>th</sup> June. An updated timetable will be	<b>CJS &amp;</b>

circulated to SAC chairs (also see item 7.)

6.2. **Website Update**

6.2.1 **DSG live on the website**

BMc informed JPAC that there had been technical problems with DSG on the website.

There was a wide-ranging discussion of the issues raised by public access to the DSG which identified the following issues:

- The existence of minor variances in practice across the 4 Services.
- Locus of responsibility for where practices differ from the guidelines.
- Increased accountability that accompanies full public access.
- The need for full consideration before republishing the cadaver guidelines.

JPAC gave BMc the authority to take the DSG out of the public domain if necessary.

BMc undertook to consult and prepare a short discussion paper for JPAC.

**BMc**

6.2.2 **Freedom of Information Act**

JPAC was reminded that the freedom of information act required a publication scheme to be prepared and published. Action BMc and CJS.

**BMc &  
CJS**

6.2.3 **JPAC Resource Area**

CJS gave a brief explanation of the JPAC Resource area and the progress being made uploading all the relevant information (membership/committee/meeting details etc.) onto these pages. It is hoped that passwords will be issued to JPAC members in July.

The question of separate review of the discussion site, confidential to each SAC was raised. It was made clear that documents placed in the Discussion area, by authorised JPAC members, can be viewed by any JPAC member with a password. They may add a comment, but cannot alter the document.

6.3. **Appointment of SAC Chairs**

BMc informed JPAC that several SAC chairs were appointed more than 3 years ago and according to the JPAC constitution were due for renewal. It was agreed by JPAC that the following chairs would be re-appointed for a further 3 years.

Bruce Cuthbertson	–	SAC on Plasma for Fractionation
George Galea	–	SAC on Tissues and Stem Cells
Stan Urbaniak	–	SAC on Immunohaematology
Liz Love	–	SAC on Transfusion Transmitted Infection

PA had tendered his resignation as chair of SACIT as he has recently been appointed, on a part-time basis, as the Executive Director of ICCBBA Inc., the organisation responsible for the ISBT128 information standard. He commences working for ICCBBA on 1st July. He will continue to work for the Welsh Blood Service on a part-time basis and will remain based in South Wales.

BMc also informed JPAC that, after he has produced the 4<sup>th</sup> Edition of the Handbook of Transfusion Medicine, he will also be resigning as chair of the SACCTM.

BMc invited JPAC to send nominations for these 2 chairs to CJS and himself. CJS will circulate the agreed process to JPAC members for information.

6.4. **Microbiological Safety of Blood & Tissues**

VJ had asked JPAC to submit comments on the proposed reorganisation of MSBT. BMc, as the new Chair of JPAC, undertook to prepare a short paper to be circulated to JPAC and to invite comments to be embodied in the paper for discussion at the next JPAC meeting in November.

**BMc**

7. **EUROPEAN UNION DIRECTIVE**

Willie Murphy explained the complexities concerning the various EU Commissions and Regulatory Committees etc. WM agreed to produce a short paper and influence diagram explaining how these groups link together.

**WM**

There was extensive discussion about the relationships of JPAC guidelines and the relevant EU Directives, when translated into law, and whether the MHRA will inspect against the Red Book guidelines or the EU Directive.

***Post meeting note – extract taken from the minutes of the JPAC meeting held on 21<sup>st</sup> November 2003 – for information***

Chris Turner (CT) was asked whether the MHRA inspections will use the EU Directive or the Red Book in future. CT replied that as the EU Directive aims at minimum standards and the Red Book reflects the more stringent requirements in the UK, both the Red Book and the EU Directive will be used. AER stated that the Red Book is crucial for updating the EU Technical Directives.

Derwood Pamphilon reported that Tissue Laboratories, inspected by MHRA, use both the Red Book and Code of Practice for Tissues. CT replied that they will use what is available and Red Book defines best practice.

VJ will be asked to assist in the production of a list of the differences between the 7<sup>th</sup> Edition of the Red Book and the EU Directives for circulation to JPAC.

**BMc**

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

8.1. **Final summary of activity for 2003 and work plan for 2004 (JPAC Enc. 04/27)**

Circulated for information.

8.2. **Developing Prion Removal Technology, 10<sup>th</sup> May 2004 – briefing note from Dr L Williamson (JPAC Enc. 04/28)**

Circulated for information.

8.3. **RhD Grouping of Plasma – Paper from SACBC & SACIH (JPAC Enc. 04/46)**

This paper was fully discussed and warmly welcomed by JPAC. It was noted that the

	<u>Action</u>
<p>paper provides a firm evidence base for the new BCSH guidelines. JPAC agreed to await the final report, which would include the results of further experiments on plasma derived from whole plasma units, before making a recommendation to the UK Forum.</p>	<b>SM</b>
<p>8.4. <b><u>High Titre Anti-A/B Testing – Paper from SACBC &amp; SACIH (JPAC Enc. 04/47)</u></b></p> <p>BMc, on behalf of JPAC, thanked everyone involved in producing this paper which JPAC endorsed.</p> <p>JPAC agreed that its advice offered to the UK Forum would be:</p> <ol style="list-style-type: none"> <li>1. That despite the low incidence of adverse reactions it would be difficult to defend a decision to abandon testing for “high titre” donations.</li> <li>2. The recommendations in paper 04/47 would be commended to the UK Forum.</li> </ol> <p>BMc will write to the UK Forum and enclose this paper.</p>	<b>BMc</b>
<p>9. <b>STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS</b></p>	
<p>9.1. <b><u>Haemoglobin Concentration (Hb), blood donation and the EU Directive – paper by Frank Boulton (JPAC Enc. 04/30)</u></b></p> <p>FB had produced this paper pointing out that the UK Blood Services threshold for venous haemoglobin (in donors failing the copper sulphate test) was lower than that prescribed in the EU Directive. His paper argues that the UK Blood Services have however established the exceptional circumstances that would allow these criteria to be compliant with the EU Directive.</p> <p>It remains to be determined by the appropriate authority (MHRA) that the copper sulphate method will be accepted under the Devices Directive. Action: BMc to establish, from the MHRA, when a decision can be expected.</p> <p>In discussion it was pointed out that there are important differences in donor haemoglobin testing practices across the EU: for example in France the haemoglobin level is not tested before donation, but is determined on the collected blood unit. It was reported that this practice is considered by the French Authorities to comply with the EU Directive.</p> <p>FB agreed to revise the paper for redistribution to JPAC. BMc will send the discussion paper to the MDs highlighting the issues requiring decisions.</p>	<b>BMc</b>
<p>9.2. <b><u>Re-appraisal of the Donor Age Criteria for the UK with recommendations – paper by Frank Boulton (JPAC Enc. 04/31)</u></b></p> <p>FB asked JPAC to send their comments on this paper to him by the end of August and the issue will be discussed at the next JPAC meeting in November.</p> <p>FB will also report on the evidence base for donor selection criteria so far at the next JPAC meeting in November.</p>	<b>ALL &amp; FB</b>
<p>10. <b>STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE</b></p>	

**Action**

The 4<sup>th</sup> Edition of the Handbook of Transfusion Medicine is in progress. BMc reported that the UK Services Systematic Review Group is contributing to the documentation of the evidence base.

**11. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

**Donor/patient consent to provide materials for reagents**

Due to lack of time JPAC were unable to discuss this issue. SU to send a copy of his letter regarding this issue to BMc. This will be placed on the agenda of November's JPAC meeting.

**BMc  
CJS**

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

**12.1. Chair of SACIT**

Discussed under item 6.3.

**12.2. NHSIA Contract to Support the Dictionary of Medicines and Devices (dm+d)**

Noted that this will not be pursued by the National Blood Service.

**12.3. SACIT Recommendations on the Rollout of ISBT 128 – paper to be submitted to the UK Forum (JPAC Enc. 04/36)**

BMc, on behalf of JPAC, thanked the SACIT for this paper. JPAC endorsed its recommendations. BMc to send to the UK Forum.

**BMc**

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

Nothing to report.

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

14.1. LL reported that EOR with, appropriate expert advice, have completed two papers:

- 1) vCJD infection risks of bone products: A comparative assessment
- 2) On the risk of vCJD transmission via donated tissues or stem cells: Preliminary analysis

The paper on bone was commissioned by the NBS Blood and Tissues Safety Assurance Group (BTSAG) and the paper on tissues by SACTTI and SACTSE. Both papers have received wide input and have been seen and commented upon by SEAC and MSBT. MSBT has set up two consultation processes, one for bone and one for tissues – both will report back to MSBT.

LL will circulate the papers to JPAC for information. **These papers are strictly not for further dissemination.**

**LL**

**Action**

14.2. **TEARS**

GG gave a brief update on TEARS following his papers to the last JPAC meeting in February.

Action: BMc to request GG, as chair of SACTSC, to produce a brief report with recommendations for the next JPAC meeting in November, or the February 2005 meeting.

**BMc**

14.3. **Council of Europe (CoE)**

There is a requirement to improve the relationship between the SACTSC and the CoE so that appropriate input into the CoE guidelines can be done in a timely manner. Action BMc.

**BMc**

14.4. **Human Tissue Bill**

It was noted by GG that whilst the Human Tissue Bill is undergoing due process in England, the legislation will not apply to Scotland. This may have impact on the role of the Human Tissue Authority and inspections of the Tissue Banks in Scotland.

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

15.1. **Microbiology Testing for Tissue and Stem Cells Donors**

LL informed JPAC that this topic is under discussion by three groups:

- HPA Working Group - chaired by Professor Duerden.
- WHO Working Group
- SACTTI Sub-Committee - chaired by Phil Yates

GG had attended the HPA Working Group meeting.

Phil Yates' summary paper, Microbiology Testing for Tissue and Stem Cells Donors (JPAC Enc. (04/41), was circulated for information. It was felt to be desirable that the finished paper be received by JPAC so it can be discussed at the JPAC meeting in November.

**LL**

15.2. **SACTTI Membership/Observers – Ireland**

JPAC agreed that LL could invite Dr Joan O'Riordan from the IBTS to join SACTTI.

**LL**

Any proposals for additional external participants/observers to JPAC/SAC meetings must be agreed by JPAC.

- Individuals would be invited for their expertise.
- Individuals would meet all their own expenses.
- External participants/observers would be agreed only in very exceptional circumstances.

15.3. **Minutes of the SACTTI Group on Blood Parasites held on 13<sup>th</sup> May 2004 – JPAC Enc. 04/43**

*(This discussion was curtailed through lack of time)*



LL presented the following 2 recommendations from the minutes of this group:

15.3.1 **Leishmaniasis** (page 3, item 4.1.)

“During the months that the paper has been under consideration no cases of visceral leishmaniasis have been recorded in Iraq. There is no risk of transfusion transmission from cutaneous Leishmaniasis. There is therefore no logic in deferring for cutaneous Leishmaniasis for personnel returning from Iraq. In addition leucodepletion probably plays a role in reducing the risk of transmission of Leishmaniasis, as discussed in the SACTTI document”

***Recommendation: There is no scientific or medical indication to change practice from current guidelines for donor selection in relation to Leishmaniasis.”***

This recommendation was endorsed by JPAC.

15.3.2 **Malaria** (page 5, item 6.3.)

***Recommendation: The residency rule should be changed to allow re-entry only on the basis of a negative MAT no earlier than 6 months from return to the UK. The premise that “Once a resident, always a resident” should remain.”***

This recommendation was endorsed by JPAC.

It was agreed that BMc would send both these recommendation to the UK Forum.

**BMc**

15.4. **Discussion Document: Deferral of plasma product recipients from blood and tissue donation – JPAC ENC 04/48**

The UK Forum had requested this paper at their meeting on 21<sup>st</sup> May. BMc, on behalf of JPAC, wished to thank Marc Turner’s group for their work on this paper.

BMc will send this paper to the Medical Directors of the 4 Blood Services and, in view of the imminent MSBT meeting, it was agreed with MM, as chair of the UK Forum, that a copy should be sent at the same time to Professor Lindsey Davies chair of MSBT.

**BMc**

15.5. **Emerging Infections – National Expert Panel on New and Emerging Infections**

This would be discussed at the next JPAC meeting in November.

**CJS**

16. **ITEMS RAISED BY NIBSC**

No items were raised.

17. **ITEMS RAISED BY MHRA**

No items were raised.

18. **ITEMS RAISED BY UK TRANSPLANT**

No items were raised.

19. **ANY OTHER BUSINESS**

No items were raised.

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

**Please note: Change of date and venue**

The next meeting will take place on Wednesday 10<sup>th</sup> November 2004 at BMA House in London.

**The meeting closed at 16:10**