APPROVED 26/10/2005

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 32nd Meeting held at the West End Donor Centre, London, on Wednesday 22nd June 2005

Meeting commenced at 10:55 am

PRESENT

Dr Frank Boulton	**(FB)**	-	Standing Advisory Committee on Care and Selection of Donors
Prof. Ian Franklin	**(IF)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr David Hutton	**(DH)**	-	Standing Advisory Committee on Care and Selection of Donors
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Dr Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
Dr Liz Love	**(LL)**	-	Standing Advisory Committee on Transfusion Transmitted Infection
Dr Sheila MacLennan	**(SM)**	-	Standing Advisory Committee on Blood Components
Dr Brian McClelland	**(BMc)**	-	Professional Director of JPAC **(Chair)**
Dr Morris McClelland	**(MM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Willie Murphy	**(WM)**	-	National Medical Director, Irish Blood Transfusion Service
Dr Derwood Pamphilon	**(DP)**	-	Standing Advisory Committee on Stem Cells
Miss Caroline J Smith	**(CJS)**	-	JPAC Office Manager **(Minute taker)**

Action

1. APOLOGIES

Dr Bruce Cuthbertson	**(BC)**	-	Standing Advisory Committee on Plasma for Fractionation
Dr Morag Ferguson	**(MF)**	-	National Institute for Biological Standards and Control
Dr George Galea	**(GG)**	-	Standing Advisory Committee on Tissues
Ms Barbara Morris	**(BM)**	-	Medicines and Healthcare Products Regulatory Agency
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Mr Stuart Penny	**(SP)**	-	Standing Advisory Committee on Information Technology
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

2. NEW SAC CHAIRS

BMc welcomed two new SAC Chairs to their first JPAC meeting - Dr David Hutton, Standing Advisory Committee on Care and Selection of Donors and Dr Derwood Pamphilon, newly created Standing Advisory Committee on Stem Cells

Apologies were received from Mr Stuart Penny who has accepted the Chair of the Standing Advisory Committee on Information Technology and Dr Derek Norfolk who has accepted the Chair of the Standing Advisory Committee on Clinical Transfusion Medicine

Action

3. MINUTES OF THE MEETING ON 23RD FEBRUARY 2005

The minutes of the last meeting were approved.

4. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 05/32

4.1. **Shelf life of red cells in additive solution (SAG-M) JPAC 05/04 updated – item 4.1.**

An updated version of the SACBC paper JPAC 05/04 was approved at the UK Forum meeting held on 24th May 2005.

4.2. **Specifications for buffy coats – item 4.3.**

Agenda item for JPAC meeting on 26th October 2005. **CJS**

4.3. **SAC Summary of activities 2004 and Work Plans 2005 – item 4.4.**

Received.

4.4. **Deferral for blood donors recently immunised with vaccines (JPAC 05/07) – item 5.1.**

This paper was approved at the UK Forum meeting held on 24th May 2005.

4.5. **Expiry dates on JPAC Position Statements – item 5.2.**

Agenda item for JPAC meeting on 26th October 2005. **CJS**

4.6. **West Nile Virus: Position Statement, version 5, 8th December 2005 – item 5.3.**

Published on the web site.

4.7. **EU Blood Directive rules for the deferral of malaria risk donors – item 5.5.**

Documents prepared by Australia and the draft of the next CoE guide sent to SACTTI and SACCSD.

4.8. **Proposed Red Book standards for arm cleansing and monitoring, diversion and bacterial detection (JPAC 05/12) – item 5.6.**

This paper was approved at the UK Forum meeting held on 24th May 2005. Also discussed under item 5.1.

4.9.
- **Validation of red cell and plasma quality following Prion Removal (JPAC 05/13) – item 5.8.1.**
- **SACTTI vCJD Working Group – Validation of efficacy of prion removal filters (JPAC 05/14) – item 5.8.2.**
- **Prion Removal Working Group – Prion removal devices: Interim operational specification (JPAC 05/15) – item 5.8.3**

The Chair of JPAC wrote to Dr Lorna Williamson on 8th March 2005 conveying JPAC's approval of these papers

4.10. **Malaria rules: Changes in geographical risk in relation to the Tsunami disaster zone – item 5.9.**

Action

Change Notification issued 12th April 2005.

4.11. **Issues requiring action from the SAC on Care and Selection of Donors - Items 7.2. to 7.5.**

DH and BMc will produce a work plan, for the next JPAC meeting on 26th October 2005, which will take account of all the outstanding SAC on Care and Selection of Donors issues. **DH, & BMc**

4.12. **Framework for evaluation of pathogen reduction of blood components – item 8.1.**

A teleconference took place between BMc, LL and SM to decide how to take this forward.

It was agreed that the paper should be completed for submission to JPAC for consideration at the next meeting on 26th October 2005. **SM & LL**

4.13. **High Titre Anti-A/B Testing – item 8.3**.

CJS to e-mail SU to find out what progress has been made with this issue. **CJS**

4.14. **Calculated microbial risk from blood transfusion – item 8.6.**

A short position statement identical to information now on the HPA web site will be posted on the JPAC web site. **CJS**

4.15. **Update on upper limit of pH – item 8.8.**

SACBC is still awaiting information from BEST (Biomedical Excellence for Safer Transfusion). **SM**

5. UK FORUM UPDATE – JPAC 05/33

Morris McClelland went through his report from the UK Forum meeting which took place on 24th May 2005.

5.1. **Proposed Red Book standards for arm cleansing and monitoring, diversion and bacterial detection (JPAC 05/12)**

This will be issued as a position statement and further consideration will be given by SACTTI to means of monitoring the effect of the procedures.

Action : BMc to discuss with Philip Mortimer and LL **BMc & CJS**

5.2. **ISBT 128 Timetable**

The UK Forum had felt that this was not a high priority. However, in discussion there was some concern that delays could lead to operational problems. It was agreed that this would be discussed with SP the new chair of SACIT. **BMc, SM & SP**

Action: SM and BMc

5.3. **Donation archive storage times**

AER (NBS) has arranged a meeting on patient samples – storage, consent and confidentiality which will take place on 13th July to which the other Services have been invited. JPAC will scrutinise the outcomes from this meeting.

Action

BMc will do a short paper regarding these issues for the UK Forum meeting on 4th November 2005.

BMc

6. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION

6.1. **Transfusion transmissible infectious agents: basis for a policy framework – JPAC 05/36 Summary sheet & JPAC 05/37 Paper**

JPAC endorsed this paper as a working draft.

The following points emerged from the discussion:

- The paper should be reviewed in June 2006
- We should invite comment and input from external organisations.
- The paper should be placed on the JPAC web site and comments invited.
- The processes outlined would fit into the overall framework proposed in the ESOR paper entitled "A framework for NBS blood and tissues safety decisions June 2005", prepared for the BTSAG.
- There may need to be some clarification as to which issues covered in the paper are specific to blood, tissues or both
- There may be a need for a supplementary document showing how the framework would be used in both urgent and non-urgent issues.

Action: LL **LL**

Action: Paper to MSBTO

Post meeting note: Paper sent to the MSBTO secretariat for their information prior to the meeting on Tuesday 28th June.

6.2. **Recommendations for Revision of Microbiology Testing Requirements for Tissue and Stem Cell Donors – JPAC 05/34 Summary sheet & JPAC 05/35 Paper**

Phil Yates arrived at 12:00. BMc welcomed PY who will present his paper and represent GG Chair of SACT in his absence.

PY went through the recommendations in this paper which JPAC accepted. The following issues arose in discussion and may need to be incorporated in the document in a future revision:

- sample archiving
- donor consent
- inclusion of therapeutic cells and autologous stem cells donations – DP agreed to produce a short draft paper Action: DP **DP**
- need to validate tests for use of cadaver blood (amendment now made)
- LL will send recent comments received from Richard Tedder to Phil Yates **LL**
- issues relating to rabies and other zoonoses will be considered at the next SACTTI. **LL**

Action: LL to update paper and sent to CJS to forward to MSBTO secretariat for their meeting on Tuesday 28th June.

Post MSBTO meeting note: Recommendations 5.1. (option to drop the 6 month quarantine sample) was approved by MSBTO subject to further confirmation from GG that this would not lead to any loss of safety with regard to any relevant organism.

Action: GG **GG**

Action

6.3. **Rabies and blood donation/tissue transplantation – JPAC 05/38 Summary sheet & JPAC 05/39 Paper**

LL and DH to develop the Donor Selection Guideline entry from this guidance. **LL & DH**

It was felt that there was a need for better surveillance of recipients of tissues and organs with respect to possible transmission of these infections. BMc undertook to raise again the matter of a SHOT type system for tissues with Dorothy Stainsby. **BMc**

6.4. **Donor selection guidelines for major surgery and endoscopy - JPAC 05/40 Summary sheet & JPAC 05/41 Paper**

This paper was circulated to JPAC for information.

6.5. **MRSA carrier status and risk in relation to blood donation – JPAC 05/42 Summary sheet & JPAC 05/43 Paper**

JPAC endorsed the recommendations in this paper.

Post meeting note: BMc sought the opinion of MSBTO on this recommendation on 28th June. MSBTO requested that the paper be circulated to MSBTO members for comment before a decision was taken to implement the recommendation. Paper circulated on 6th July 2005.

6.6. **West Nile Virus Position Statement, Version 6 – JPAC 05/44 Summary sheet & JPAC 05/45 Paper**

This position statement is an interim update to fit in with the FDA and will be posted on the web site.

Post meeting note: Posted on the JPAC web site on Friday 8th July 2005.

6.7. **SACTTI Working Party on Parasitology and Blood Safety – draft minutes of the meeting on 12th May 2005 – JPAC 05/46**

LL went through the recommendations of the working party and the following comments were made by JPAC.

Leishmaniasis

Recommendation: No change to donor selection guidelines

JPAC comment - the words "tissues or blood" should be added to the recommendation. **LL**

Malaria

Recommendation: Further assays should be evaluated for confirmatory testing.

LL informed JPAC that Alan Kitchen is doing this for the NBS.

Recommendation: More active management of sero positive donors should be pursued and policies should be developed.

Action: DH to place on SACCSD work plan. **DH**

BMc to send SACTTI comments to Albert Furrugia's on the paper prepared by Australia for this years Council of Europe meeting - Risk of malaria from blood transfusion – role **BMc**

Action

of malarial testing**.**

BMc to propose to Karl-Freidrich Bopp that a parasitology expert, possibly Peter Chiodini, should attend the next Council of Europe SP-GS meeting. **BMc**

6.8. **SACTTI report from meeting 17th May 2005 – NBS NAT Strategic Review – JPAC 05/47 Summary sheet & 05/48 Paper**

This paper was circulated to JPAC for information.

6.9. **SACTTI recommendations and advice concerning Avian influenza and the potential threat of a pandemic – JPAC 05/58**

The NBS had requested advice and recommendations from the SACTTI on this issue. The Chair of JPAC wished to draw this paper to the attention of the Medical Directors of the other 3 Blood Services at this meeting, especially with regard to contingency planning.

Action: SACCSD to clarify issue with regard to people treated with prophylaxis. **DH**

6.10. **SACTTI (vCJD sub-committee) recommendation to change rules for donors with a history of transfusion (since 1st January 1980) to extend geographical areas for exclusion – JPAC 05/59**

JPAC endorsed this paper and agreed that it should be sent to the MSBTO for their next meeting, noting that it needs some impact assessment.

Action: LL to add BSE cases to this paper. **LL**

Action: Paper to MSBTO

Post meeting note: Paper sent to the MSBTO secretariat for their information prior to the meeting on Tuesday 28th June. MSBTO noted this advice.

7. STANDING ADVISORY COMMITTEE ON TISSUES

7.1. **Comments by the SACT on annex 1 of the EU Directive – email from George Galea to Triona Norman – JPAC 05/49**

Circulated to JPAC for information.

8. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

8.1. **Deviations from 4^0 temperature storage for red cells - effect on viability and bacterial growth – JPAC 05/50**

This paper was approved at the UK Forum meeting on 24th May 2005.

8.2. **RhD grouping of Fresh-Frozen Plasma (FFP) – JPAC 05/51**

This paper was approved by JPAC. The Chair will take these recommendations to the next Council of Europe SP-GS meeting. **BMc**

8.3. **EU Directive – Labelling of components – JPAC 05/52**

Barbara Morris could not attend this JPAC meeting. SM informed JPAC that she had discussed this issue with BM at length and could update JPAC on the current situation.

Action

SM, BC and BMc had produced this paper, at very short notice, for BM to take to a Medicines and Healthcare Products Regulatory Agency (MHRA) meeting on 18th April, at which this issue was to be discussed. Unfortunately this meeting was cancelled, but BM has circulated this paper to the relevant people at the MHRA.

Action: SACBC to link with SACIT to advise on what wording changes need to be on the labels and to alert the operational people in the 4 Blood Services that there will be a change. **SM & SP**

8.4. **EU Directive and changes to specifications and monitoring – JPAC 05/61**
Update on leucodepletion residual risk in the UK (for information) – JPAC 05/62
Leucodepletion risk trends in the UK (for information) – JPAC 05/63

SM went through JPAC 05/61 and supporting papers 05/62 and 05/63.

JPAC accepts the following recommendation in JPAC 05/61

- It is recommended that the current UK LD specification is retained but augmented with an additional requirement at a specified limit of $1x10^6$/unit. The UK specification would become:

  $<5x10^6$leucocytes/unit in >99% of components with 95% confidence and >90% of components $<1x10^6$/unit

A question was raised as to whether testing <100% of components provides adequate security. It was pointed out that testing100% of all components for adequate leucodepletion was probably logistically and financially non-feasible. It was also questioned as to whether 100% testing was appropriate for a measure intended to reduce risk rather than to remove it (as in the case of viral marker screening).

JPAC wished further risk assessment – Action NBS to be requested for access to ESOR analysis to do this work. Action BMc. **BMc**

8.5. **Platelet storage temperature limits – JPAC 05/64**

Proposed Recommendation:

Platelets that are temporarily stored for a cumulative period of 12 hours between 18 and 30 ^oC , outwith the recommended 20 to 24 ^oC , still provide an acceptable therapeutic product.

This paper addressed functional quality of platelets only. JPAC sought further data about the possible effects of these modified storage conditions on sterility.

Action: SM to consider in conjunction with SACTTI and report back to JPAC. **SM &LL**

8.6. **Evaluation of novel platelet components – JPAC 05/65**

JPAC endorsed the SACBC recommendation with a few minor amendments.

Action: Include criteria for evaluation in the “Red Book”. **SM**

8.7. **Summary: Evaluation of platelet additive solutions for the storage of pooled platelet concentrates – JPAC 05/66**
Report: Evaluation of platelet additive solutions for the storage of pooled platelet concentrates (additional information to accompany the above paper JPAC 05/66) – JPAC 05/67

Action

JPAC are asked to endorse the inclusion of a specification for platelets in additive solution in the Red Book based on this in vitro data. Blood Services will need to demonstrate validity of individual pack systems and additive solutions prior to implementation.

JPAC endorsed the SACBC recommendation.

Action: Include specification for platelets in platelet additive solution in the "Red Book". **SM**

8.8. **Collation of data on concessionary issues – JPAC 05/68**

SACBC proposed that the data on "concessionary" issues of blood components should be collected and analysed.

It was noted that figures for Scotland should be available from the chair of Clinical Governance Committee SNBTS.

The above request was approved.

Action: BMc check and consult on the BSQR 2005 with respect to "novel" products. **BMc &**
SM to contact Sam Rawlingson regarding figures for Scotland. **SM**

8.9. **Membership on ISO Committee on blood pack specifications – JPAC 05/69**

Membership of this committee was discussed. It was noted that the committee is mostly made up of commercial representatives. Mr Mark Nightingale who works for the NBS, and is a member of the SACBC Technical Group, appears to be the only Blood Service member.

Action: SM to discuss membership of this committee with Martin Bruce. **SM**

8.10. **Plasticisers (DEHP)**

SM to write to manufacturers for their position statements. **SM**

BMc literature search to be sent to SM. **BMc**

8.11. **Prion Reduction Devices – JPAC 05/70**

BMc and SM will discuss where best to published these papers. **SM & BMc**

9. **JPAC EXECUTIVE WORKING GROUP MEETING - 26TH MAY 2005**

Draft minutes of this meeting are with the group and when confirmed will be circulated to JPAC. **CJS**

10. **WORKSHOP FOR JPAC CHAIRS – 16TH JUNE 2005**

BMc to circulate the outcomes of this meeting for comments. **BMc**

11. **7th EDITION OF THE RED BOOK – UPDATE**

Manuscript of the 7th edition of the Red Book is now at the Stationery Office. First proofs should be ready in early July.

Action

12. **WEB SITE REPORT**

Nothing new to report.

13. **ANY OTHER BUSINESS**

No items were discussed under AOB.

The meeting closed at 15:30

14. DATE AND VENUES OF FUTURE JPAC MEETING

- Wednesday 26th October at the West End Donor Centre in London

2006

- Wednesday 1st March at the West End Donor Centre in London
- Wednesday 21st June at the West End Donor Centre in London
- Wednesday 1st November – venue to be confirmed