APPROVED 01/03/2006

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 33rd Meeting held at the West End Donor Centre, London, on Wednesday 26th October 2005

Meeting commenced at 10:55 am

PRESENT

Dr Frank Boulton	**(FB)**	-	Standing Advisory Committee on Care and Selection of Donors
Mr David Churchward	**(DC)**	-	Medicines and Healthcare Products Regulatory Agency (Observer)
Prof. Ian Franklin	**(IF)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr George Galea	**(GG)**	-	Standing Advisory Committee on Tissues
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 Infections
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
Ms Barbara Morris	**(BM)**	-	Medicines and Healthcare Products Regulatory Agency
Dr Willie Murphy	**(WM)**	-	National Medical Director, Irish Blood Transfusion Service
Dr Derwood Pamphilon	**(DP)**	-	Standing Advisory Committee on Stem Cells (10:55 to 14:00)
Miss Caroline J Smith	**(CJS)**	-	JPAC 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 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. MINUTES OF THE MEETING ON 22nd June 2005

Minutes of the last meeting were approved.

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 05/71

3.1. **Issues requiring action from the SAC on Care and Selection of Donors – Item 4.11.**

These items have been added to the SACCSD work plan and are being progressed.

Action

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

This is a very complex issue and it was agreed that LL and SM would produce a short paper summarising the position to date for the next JPAC Executive on 8th February 2006. **LL & SM**

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

Work in progress. **SU**

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

SM informed JPAC that this has been reviewed by BEST (Biomedical Excellence for Safer Transfusion). The question asked was "is 7.4 a realistic upper limit?". The data in the BEST review is encouraging, but this is confidential.

Action: SACBC to prepare a recommendation on the upper pH limit for platelet concentrates for consideration by JPAC. **SM**

3.5. **Consent and Confidentiality – item 5.3.**

This item originated from a discussion on donation archive storage times.
Dr Angela Robinson had organised a seminar "Consent and Confidentiality: Issues Surrounding the Testing and Storage of Patient and Donor Samples" which was held on 13 July 2005 at the Royal College of Pathologists. The meeting was organised by the National Blood Service, but was also attended by representatives from the other UK Blood Services, HTA, HPA, RCPath, UKT, a legal adviser and customer hospitals. A report has been sent to attendees.

Post meeting note: Angela Robinson's summary of this meeting was circulated by CJS to JPAC for information on 10th November 2005.

3.6. **Transfusion Transmissible infectious agents: basis for a policy framework (JPAC 05/37) – item 6.1.**

This paper has been completed, although it will inevitably evolve. It will be used by SACTTI as a framework for evaluating new pathogens. An abbreviated version will be submitted for publication (Action: BMc). **BMc**

LL was asked to convene a small group to look at what amendments are needed to make the next version of this paper applicable to tissues and cells. (Action: LL).

Post meeting note: The first meeting (video conference) will take place on 19th January 2006. (Membership: Liz Love, Peter Simmons, Roger Eglin, Derwood Pamphilon, Richard Tedder and Phil Yates)

It was noted that the paper does not specify the decision-making processes and responsibilities. Relevant aspects of this will be included in the JPAC review proposals (Action: BMc). **BMc**

3.7. **Recommendations for Revision of Microbiology Testing Requirements for Tissue and Stem Cell Donors – item 6.2.** (see also minute 6.)

DP had agreed to produce a short draft paper on the inclusion of therapeutic cells and autologous stem cell donations. This would be ready for the next JPAC meeting in March 2006. **DP**

Action

DP enquired about the section dealing with malaria testing on cord blood. LL stated that the recommendations of the SACTTI Working Party on Parasitology and Blood Safety had previously been agreed by JPAC and incorporated.

Post Meeting Note: Further questions on this section have been referred to the next meeting of the Working Party on Parasitology and Blood Safety in May 2006.

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

Leishmaniasis - A brief entry for the relevant DSGs to be prepared by SACCSD. **DH**

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

As requested the SACCSD have clarified this issue with regard to people treated with prophylaxis.

Post Meeting Note: SACTTI has been asked by Richard Bedford (in charge of Emergency Planning for NBS) to provide guidance on infection control with respect to donor sessions. Action SACTTI. **LL**

4. UK FORUM UPDATE – JPAC 05/72

4.2. **Disability Discrimination Act**

Clarification on this item in 05/72 was sought.

"*As donors are customers we cannot refuse their donations except for good, evidence based reasons. Advice from SAC (CSD) was somewhat at variance with this opinion.*"

This was to be discussed at the next UK Forum meeting.

Post meeting note: UK Forum agreed, at their meeting on 4th November, to refer this back to SACCSD and clarified the following:

- *Its concern was that any "blanket" exclusion on the grounds of disability would not be acceptable or legal.*
- *Decisions with respect to individual donors must comply with the accepted principles of safeguarding both donor and recipient.*
- *Decisions on donor acceptance or deferral should be based, as far as possible, on objective evidence.*
- *The criteria of responsibleness and practicability should apply.*

4.3. **Issues from NIBSC**

JPAC was informed that a consultation process on the proposed merger of NIBSC with the HPA is in progress and responses from stakeholders must be received by 31st December 2005.

JPAC undertook to send the National Institute for Biological Standards and Control, Corporate Plan, 2005-2010, Executive Summary to the Medical Directors of SNBTS,

Action

WBS and NIBTS (Action: CJS).

Post meeting note: Executive Summary e-mailed to MDs on 15th November 2005.

4.4. **Risk information relating to blood components**

It was noted, and discussed, that there is now an inconsistency in the labelling of tissues and blood components with respect to vCJD risk. It was agreed that this matter should be raised again with the UK Forum on 4th November by BMc.

Post meeting note: UK Forum agreed that JPAC should be requested to prepare a plan for the UK Services to inform prescribers (and? patients) of vCJD risks. This plan should be approved by all the Services within 12 months of the first use of the vCJD risk labels being applied to tissues (March 2005).

5. REPORT ON JPAC REVIEW

The JPAC Chair reported on the progress of the JPAC review. The latest draft will be circulated to JPAC when available. **BMc**

6. STANDING ADVISORY COMMITTEE ON STEM CELLS

6.1. **Briefing paper for the British Society of Blood and Marrow Transplantation response to the Human Tissue Authority's (HTA) Codes of Practice - JPAC 05/104**

This paper was circulated for information. DP informed JPAC that the HTA have agreed that haemopoietic stem cells will be withdrawn from this code of practice. BMc asked DP to keep JPAC updated.

Post Meeting Note: The HTA have decided not to withdraw haemopoietic stem cells from the codes, but to put them in a separate section.

6.2. **European Union Directive on Tissues and Cells 2004/23/EC update on implementation - JPAC 05/105**

This paper from the Department of Health outlined the timetable for the Tissues Directive and the UK Regulations. In discussion it appeared that even this recent timetable my now have altered.

JPAC Chair to request updated information on the timetable from the MHRA and the Department of Health. Action: BMc and CJS. **BMc & CJS**

7. REPORT FROM MSBTO MEETING ON 18TH OCTOBER 2005

The Chair gave a verbal report from the MSBTO meeting and agreed to circulate the summary and actions from this meeting to JPAC when they become available. **BMc**

The main items which concerned JPAC are:

- Deferral of tissue recipients from donating blood and tissues
- Deferral of cadaveric donors of musculo skeletal tissues
- Living donors of surgical tissues
- Definition of tissues
- Update on testing of cadaver tissue for PrPsc

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- Microbiological testing of blood samples from organ donors prior to organ transplantation
- Revision of microbiology testing requirements for tissue and stem cells donors
- Microbiological safety of pasteurised breast milk
- Decision framework
- HCV testing
- Prion removal from blood components
- MRSA – information for UKBTS staff
- Move to review device status of putative prion tests

Post meeting note: The paper "Definitions of Human Cells, Tissues and Organs", submitted to the MSBTO on 18th October 2005, was circulated to JPAC on 10th November 2005.

8. COMMONALITY IN COMPONENTS - UPDATE

JPAC discussed progress towards achieving a common catalogue of blood components and common labelling systems that comply with the requirements of the Blood Safety and Quality Regulations 2005. This work is being taken forward by SACBC, SACIT and the 4 Services.

JPAC endorsed this work.

Proposals for labelling to comply with BSQR have been agreed by the Services and will be forwarded to MHRA together with a report from each Service on the anticipated date from implementation (Action: SACBC).

Post meeting note: This information was sent to BM at MHRA via CJS on 4th November 2005.

9. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

9.1. Granulocytes from whole blood donations (Confidential unpublished data) – JPAC 05/73

A report was presented on the invitro characteristics of pooled granulocyte concentrate prepared by a modified method developed by NBS Blood Developments Group. This report proposed that this product should be made available in place of the existing pooled granulocyte product and that it should be included as a new component specification within the "Guidelines for the Blood Transfusion Services in the UK" (Red Book).

Following extensive discussion it was agreed that further work is required before this product can be considered for inclusion in the Red Book.

Points raised in the discussion included:

- This product should be given a provisional status subject to specific rules – broadly along the lines of an Investigative New Drug (IND).
- A preference was expressed for initially making the product available only in the context of a planned randomised clinical trial.
- Further detailed consideration needs to be given to the case for and against making this product available outside the randomised clinical trial and the restrictions that would be required, such as the requirement to complete a case report form for a prospective register of treatment.

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It was pointed out that the decisions on the use of the new product, verses the current preferred product (granulocytes from boosted apheresis donors), must take due account of the potential risks to healthy donors, as well as any evidence for different levels of clinical effectiveness of the two types of product.

Action: A further report and proposals is required - SACBC and JPAC Chair. **BMc & SM**

9.2. **Cryoprecipitate pooled, leucocyte depleted – JPAC 05/74**

After discussion this paper was accepted on the basis that the pooled cryoprecipitate component does not differ in any essential features in its preparation from the unpooled component. It was noted that there is a possibility that the pooled components might occasionally be subjected to an additional freeze and thaw step.

Action: SACBC to consider whether an additional statement is required in the product specification which takes this into account. **SM**

9.3. **Platelets, suspended in plasma/additive solution – JPAC 05/75**

This paper was approved by JPAC. The specification will therefore be included in the "Guidelines for the Blood Transfusion Services in the UK" and on the JPAC web site.

Action: SM and CJS **SM & CJS**

During discussion of this paper the issue of the statistical basis of sampling for quality assessment was raised. There was agreement that this is a fundamental issue that requires to be re-examined with the intention of producing explicit and well founded guidance on protocols.

Action: JPAC Chair and SACBC. **BMc & SM**

9.4. **Council of Europe specification for FFP**

SM asked BMc if she could have the Council of Europe data which supports extending the shelf life of FFP to 3 years. BMc will investigate the origin of this data at the CoE. **BMc**

10. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

10.1. **MSM**

There was discussion of the continuing dissatisfaction expressed by the gay community about the current donor selection rules. These concerns are being expressed in a number of countries and a report had been produced for the EBA. It was reported that, in response to a request via Angela Robinson by MSBTO, SACTTI is working on updating the epidemiological data for a paper to be presented to MSBTO in January 2006.

Action: A Position Statement will be developed by Dr Frank Boulton with input from SACTTI. **FB & LL**

Post meeting note: This issue will be discussed in detail at the next meeting of the SACTTI on 15th November 2005.

10.2. **Critical entries to the DSG made to comply with the Blood Safety and Quality Regulations 2005**

DH informed JPAC that no adverse comments had been received to the list of critical

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entries which had been circulated to JPAC.

10.3. **Treatment for high blood pressure - JPAC 05/77**

Following discussion this paper was approved.

10.4. **Proposed changes to Donor Selection Guidelines**

Tissue and organ recipients - JPAC 05/78

This paper to be cross-checked against decisions from the MSBTO meeting on 18h October. It does not require further consideration from JPAC.

Action: SACCSD, when information is received from MSBTO. **DH**

Prion associated diseases - JPAC 05/79

This change was approved by JPAC.

Animal bite - JPAC 05/80

This is a complex issue which needs agreement between SACCSD, SACTTI, SACT and SACSC (Action SACCSD). It will then come back to JPAC for formal approval. **DH**

10.5. **Report from the SAC on Care and Selection of Donors - JPAC 05/76**

- Post donation information - Appendix 3 of the whole blood donor selection guidelines. We wish SACTTI to urgently review this appendix with regard to influenza but to also consider review of the entire document. **LL**
- Travel Index – should be completed by early in the New Year. This is in co-operation with Health Protection Scotland.

During discussion of the travel index and travel related donor exclusions, concern was expressed by MHRA about the operational reliability of discretionary malaria antibody testing.

Post meeting note: This matter is under active review by the NBS BTSAG

11. STANDING ADVISORY COMMITTEE ON TISSUES

11.1. **SACT response to the Human Tissue Authority draft codes of practice for consultation - JPAC 05/81**

This paper was tabled for information.

11.2. **Draft minutes from the MSBTO sub-group on Bone and Tissues meeting held on 22nd September 2005 - JPAC 05/82**

This paper was tabled for information.

11.3. **European Commission: Informal meeting related to blood, tissues, cells and organs held on 29th July 2005 - JPAC 05/83**

The Chair of SACT had attended this meeting as an invited participant.

It was noted that this paper laid down a useful agenda of issues relating to tissue transplantation and that the commission had been disappointed with the lack of bids for funds available for projects related to tissues under the public health research

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programme. (The related commission work plan was attached as Appendix 2 of paper 05/83)

11.4 **SACT comments on tissues directive technical requirements annex - JPAC 05/84**

Chair of SACT noted that there is considerable debate on the environmental standards in connection with open procedures. The final outcome of these deliberations is not yet decided.

No action is required by JPAC.

12. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

12.1. **Rabies and Blood Transfusion/Tissue Transplantation: SACTTI paper for JPAC, version 1.4, revised 12th October 2005 - JPAC 05/85 (Summary Sheet) & JPAC 05/86 (paper)**

Section 1.2. has been revised to simplify the wording and any reference to screening tests has been taken and out. This is reflected in the text of the document and the summary.

JPAC accepted the revised recommendations.

Action: LL will add key references and send to CJS to reformat and post on the JPAC web site.

Post meeting note: Posted on the web site as a Position Statement on 11th November 2005.

12.2. **Estimates of frequency (or risk of HIV, HCV and HBV infectious donations entering the UK blood supply 2000 - 2004 - JPAC 05/87 (summary sheet), JPAC 05/88 (paper) and JPAC 05/89 (background paper)**

This paper updates the residual risk estimates.

Post meeting note: The Position Statement was updated with this new information and was posted on the web site on 11th November 2005.

JPAC 05/89 describes a revised method of calculating residual risk. It recommends that incidents of infections in repeat donors should be derived from new infections in individuals with evidence of a previous negative donation within the preceding 3 years. This was endorsed by JPAC.

The use of this standardised definition of new infections would enable valid comparisons of risk to be made across the UK.

13. WEB SITE REPORT

- The coverage of the JPAC web site has been extended over the past 18 months to include the NHS Operational Impact Group, Better Blood Transfusion Toolkit, Evidence Library (Systematic Review Initiative) and the Educational Events Diary.
- The 7th Edition of the Guidelines for the Blood Transfusion Services in the UK and

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latest Donor Selection Guidelines are now all published on the web site.

- It is proposed to develop a forward publication schedule to give users advance information about changes and new items.
- Future developments under consideration include the provision of facilities for the National Transfusion Committees.

14. **ANY OTHER BUSINESS**

No items were discussed under AOB.

The meeting closed at 15:45

15. DATE AND VENUES OF FUTURE JPAC MEETING

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 at the West End Donor Centre in London