

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 35th Meeting held at the West End Donor Centre, London, on Wednesday 21st June 2006

Meeting commenced at 11:00 am

PRESENT

Dr Bruce Cuthbertson	(BC)	- Representing the Quality Managers of the 4 UK Blood Services
Dr George Galea	(GG)	- Standing Advisory Committee on Tissues
Dr David Hutton	(DH)	- Standing Advisory Committee on Care and Selection of Donors
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
Dr Willie Murphy	(WM)	- National Medical Director, Irish Blood Transfusion Service
Dr Derek Norfolk	(DN)	- Standing Advisory Committee on Clinical Transfusion Medicine
Dr Derwood Pamphilon	(DP)	- Standing Advisory Committee on Stem Cells
Prof. Stan Urbaniak	(SU)	- Standing Advisory Committee on Immunohaematology
Miss Caroline J Smith	(CJS)	- JPAC Manager and minute taker

Action

1. **APOLOGIES**

Dr Morag Ferguson	(MF)	- National Institute for Biological Standards and Control
Prof. Ian Franklin	(IF)	- Medical Director, Scottish National Blood Transfusion Service
Dr Stephen Inglis	(SI)	- Director, National Institute for Biological Standards and Control
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

BMc informed JPAC that this would be LLs last meeting as Chair of SACTTI and that Dr Pat Hewitt will be taking over. BMc thanked LL for all her hard work as Chair of this committee.

BMc also welcomed Bruce Cuthbertson in his new role as the Quality Manager representing the 4 UK Blood Services.

2. **MINUTES OF THE MEETING ON 1ST MARCH 2006**

Minutes of the last meeting were approved with one amendment to item 8.3. which will now read"Less than seven days from completing systemic antiviral treatment."

3. **MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 06-22**

Action3.1. **Transfusion Transmissible infectious agents: basis for a policy framework (JPAC 05/37) – item 3.2.**

Work in progress by Peter Simmonds.

3.2. **Recommendations for Revision of Microbiology Testing Requirements for Tissue and Stem Cell Donors – 3.3.**

This was discussed at length.

Actions:

- § Confirmed that a new Chapter 22 will be updated to include the agreed revisions of microbiology testing requirements for tissues (as approved by MSBTO). **GG**
- § A new Chapter 24 (stem cells) will be prepared, including revised recommendations for microbiological testing. The Chair of SACSC has already advised that the new chapter 24 should not duplicate available specialist guidelines. It was agreed that it will guide the user to relevant information that is now available from the member organisations of AHCTA (see note below) **DP**
- § The Chairs of SACT, SACTTI and SACSC agreed to ensure that these chapters will be available by the end of Oct 2006 so that the Services can prepare for implementation of the new regulations. **GG, PEH & DP**
- § Chair of JPAC to write to MSBTO to inform them of the above and that we are happy help in any way possible with the revision of the MSBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation. **BMc**

Alliance for Harmonisation of Cellular Therapy Accreditation (AHCTA)

DP informed JPAC about the AHCTA who were working together to harmonise standards.

Post Meeting Note for information: Mission Statement from AHCTA

AHCTA is formed by representatives of the following organisations:

- *European Group for Blood & Marrow Transplantation (EBMT)*
- *Foundation for the Accreditation of Cellular Therapy (FACT)*
- *International Society for Cellular Therapy (Europe) (ISCT)*
- *Joint Accreditation Committee ISCT-EBMT (JACIE)*
- *NETCORD*
- *World Marrow Donor Association (WMDA)*

The above named organisations commit themselves to the harmonisation of their respective standards with the objective of creating a single set of quality, safety and professional requirements for haematopoietic stem cell (HSC) transplantation and related cellular therapy from donation to transplantation. This commitment will be supported by collaboration on the drafting of complementary standards and guidelines; promotion of the concept of a global set of standards among the cellular therapy professional community and regulatory authorities; regular communication on all relevant issues affecting cellular therapy guidelines.

AHCTA regards regulatory authorities as partners in the application of these global standards and essential to their successful adoption and application and will endeavour to inform and support these authorities in the area of cellular therapy regulation.

3.3. **Leishmaniasis - SACTTI Working Party on Parasitology and Blood Safety – draft**

Action**minutes of the meeting on 12th May 2005 (JPAC 05/46) – item 3.4.**

No action required.

3.4. **Granulocytes – item 3.6.**

Action: Chair of JPAC to seek assistance with preparing a draft statement for the web site outlining current JPAC position on granulocyte infusions.

BMc

3.5. **Platelets suspended in plasma/additive solution – item 3.7.**

Change Notification will be issued. **Action:** SM to send CJS new text.

SM

3.6. **Statistical basis of sampling for quality assessment – item 3.9.**

The task-based team has now been set up.

3.7. **Council of Europe specification for FFP – item 3.10.**

SACBC has reviewed the evidence on which the CoE extended storage life from 2 to 3 years. There is no compelling evidence to increase storage to 3 years and therefore the SACBC recommends keeping to 2 years.

3.8. **Purpose, strategy & objectives for the SACIT – item 5.1.**

There is now an EU commission working group on nomenclature labelling and IT standards for tissues. Dr Murphy undertook to provide the information about the UK member of this group.

WM

3.9. **Commonality in blood component labelling and barcoding – item 5.2.**

The UKBTS Forum position was reiterated i.e. that the 4 UK Blood Services should standardise their blood component labels and that these should comply with the regulations. BC as representative of the Blood Services National Quality Managers undertook to take this forward with SP as Chair of SACIT.

BC &
SP3.10. **Implementation of ISBT 128**

It was understood that the UKBTS Forum position was that there should be common implementation of ISBT 128 for tissues as well as blood in the UK.

Action: Chair of JPAC to confirm at next UKBTS Forum Meeting.

BMc

GG stated that the European Commission is likely to direct that there should be a common European coding system for tissues by November 2008, and that there had been no final decision on the coding system to be proposed.

Action: Chair of JPAC to contact DoH (Dr T Norman) to request that the UK requirement to use ISBT 128 is fully communicated to the relevant body in the commission.

BMc

3.11. **Summary report on component quality of red cells filtered using the Pall prion reduction device (Leukotrap® Affinity Prion Reduction Filter, LAPRF) – item 7.2.**

DN reported on consultations with haematologists who treat patients with haemoglobinopathy, and also with NBS clinicians. There is concern among the haematologists about the balance of risk if patients require larger numbers of red cell donations as a result of a lower haemoglobin content following prion filtration.

Action**Actions:**

- § DN will provide a short report with estimates of the likely impact on donor exposure.
- § Chair of JPAC to request an ESOR review of the risk implications.

DN
BMc

3.11. **Previously Transfused Cadaver Donors – item 8.4.**

It was reported that MSBTO was in process of assembling a comprehensive table of donor selection rules intended to minimise secondary transmission of vCJD in recipients of blood, tissues or organs from individuals who may themselves have been recipients. A document prepared by the MSBTO tissues sub-group had been given general approval by MSBTO on 20th June 2006 and, following further consultation with MSBTO members, it is hoped that this will be finalised at the next MSBTO meeting in October and that there will be a clear decision at that time about dissemination and implementation.

3.12. **Disability Discrimination Act – item 8.5.**

SACCSO paper had been noted at the UKBTS Forum, but no decisions were made on specific actions.

Action: Chair of SACCSO to provide Chair of JPAC with any specific recommendations for which UKBTS Forum is asked to provide formal approval.

DH &
BMc

3.13. **MSBTO – item 10.**

Minutes from the MSBTO meeting on 24th January 2006 - No action required.

4. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS4.1. **Briefing note on the Europack Project – JPAC 06-31**

SM went through this paper for the group. **Action:** Once the final specifications have been discussed SM will bring back to JPAC.

SM

4.2. **UK Blood Services blood component leucocyte depletion – JPAC 06-32**

This is an update of a previous paper brought to JPAC. This paper is 2 years worth of data from the 4 UK Blood Services.

A lengthy discussion took place.

Actions:

- § Chair of JPAC to draft a request for ESOR to provide guidance on the levels of risk to recipients that could be associated with the different levels of leucocyte depletion achieved in current practice.

BMc

- § Chair of JPAC and SM should prepare a brief report for the UK Blood Services Quality Managers Meeting to inform them of the data and seek their views.

BMc &
SM

- § Chair of JPAC and SM to prepare brief report for November UKBTS Forum meeting.

BMc &
SM

It was agreed that this issue must be kept under close review and that it would not be appropriate to advise changes in current practice until some risk assessment information can be considered. However, the data should be shared with both the Services and the manufacturers and may be taken into account in the selection of packs.

Action5. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS**5.1. **Emerging pathogens**5.1.1. Transfusion Transmissible Infectious Agents: Blank assessment template – JPAC 06-23

This is a working document which has proved very useful. LL asked that any comments should be feedback to Pat Hewitt.

Framework is being revised for tissues etc. with Phil Yates, DP, Roger Eglin and Peter Simmonds.

Actions:

§ These risk assessments should be posted on the JPAC web site with a suitable explanatory page. **BMc**

§ Also agreed that these assessments would be offered to the National Expert Panel on New and Emerging Infections (NEPNEI). **BMc**

5.1.2. Chikungunya Virus

∅ Transfusion Transmissible Infectious Agents. Assessment template: Chikungunya Virus – JPAC 06-24

∅ Chikungunya Virus – MSBTO information sheet for 20th June MSBTO meeting – JPAC 06-25

∅ Notes of the SACTTI Task Group teleconference on Chikungunya Virus held on 13th June 2006 – JPAC 06-47

SACTTI recommended the following:

- There should be a period of deferral for asymptomatic donors returning from areas affected by Chikungunya virus which are not currently covered by malaria exclusion criteria
- A 28 day deferral period from the date of return to the UK is a reasonable and pragmatic period which is consistent with deferral for West Nile Virus and therefore may be operationally less demanding to implement.
- In the light of possible prolonged viraemia in patients who have had Chikungunya virus polyarthralgia, a pragmatic period of deferral would be 6 months from recovery, consistent with selection criteria for West Nile Virus.

These recommendations were approved by JPAC.

Action: CJS to send the Medical Directors of the 4 UK Blood Services the following:

- A brief explanatory note from the JPAC Chair
- Copy of the SACTTI recommendation approved by JPAC
- Draft Change Notification
- Background papers – Draft position statement, risk assessment template and minutes of the SACTTI teleconference held on 13th June

ActionPost Meeting Note

Change Notifications and Position Statement approved by the Medical Directors of the 4 UK Blood Services and issued on 4th July 2006.

Several members commented that they were aware of colleagues who did not know how to keep up to date with relevant information emanating from JPAC. The Chair requested that members inform the JPAC Manager of any such individuals or groups.

Post Meeting note:

This is part of the broader issue of effective "marketing" of the JPAC web site. This is being pursued by with the web site users group.

5.1.3. Influenza

- Ø Emerging pathogens risk assessments: SACTTI 05/37 Non-pandemic influenza A; SACTTI 05/42 Pandemic H5N1 influenza – JPAC 06-26
- Ø SACTTI 06/43. Further questions and answers about pandemic influenza. April 2006 JPAC 06-27

Risk assessments had been prepared and noted by JPAC on Non-pandemic influenza. The Chair of JPAC expressed the view that it would valuable for JPAC to have a concise summary of the work carried out so far. This could form the basis of a short interim position statement for publication on the web site.

Action: LL undertook to prepare this information.

LL

JPAC endorsed the following advice from SACTTI which has already been communicated to the NBS (taken from JPAC 06-27 Further questions and answers about pandemic influenza):

1. *Measures to minimise risk of transfusion-transmission to recipients: action to be taken following information about post-donation illness:-*
SACTTI withdraws its previous advice and recommends that the period for notification of post-donation influenza should be extended to two weeks from donation.
2. *Deferral of donors recovering from flu:-*
There is insufficient information on which to base any recommendation to reduce the current deferral period. On the contrary there is some evidence, extrapolating from human H5N1 (avian) influenza in humans, to suggest that there may be prolonged viral shedding and viraemia in highly pathogenic human influenza. However, as with any extreme scenario, depending on the degree of requirement, a judgement would have to be made at the time as to the balance of risks to sufficiency vs. risk to microbiological safety. Any change would require a derogation of the existing (BSQR 2005) regulation.

5.1.4. Simian Foamy Virus (SFV)

ABC newsletter, 9 June 2006 had been circulated for information.

Health Canada's Biologics and Genetic Therapies Directorate last month recommended new blood donor screening measures to reduce the theoretical risk of the transmission of SFV.

LL informed JPAC that SFV is on the SACTTI work list using the risk assessment

Action

template.

Action: Chair of JPAC thought DEFRA would be able to assist and will send a contact name to Pat Hewitt and inform NEPNEI.

BMc

5.2. **SACTTI Working Party on Parasitology and Blood Safety – minutes of the meeting held on 11th May 2006 – JPAC 06-28**

JPAC received and approved the following recommendations:

- 1.2. Leishmaniasis and tissue donors. The same selection criteria should apply as for blood donors. JPAC action – completed.
- 7.2. Malaria: Current arrangements for serological screening for malaria. (1) Further assays should be evaluated for confirmatory testing. (2) More active management of sero positive donors should be pursued and policies should be developed. Action: JPAC Chair to prepare a note for the UKBTS Medical Directors. **BMc**
- 7.3.1. Malaria and Cord Blood. If maternal malaria antibody screen is negative, there is no need to test the cord blood. Action: update the tissue micro paper. **Phil Yates**
- 8.2. Toxoplasma. (1) For whole blood and component donations, no change in the current donor selection criteria (2) For tissues – Donor selection criteria to be reviewed by SACTTI. To go on SACTTI work list. Action: BMc to notify PEH. **BMc**

5.3. **UK Position Statement: Why we ask gay men not to give blood: final version 1.0 8 June 2006. SACTTI 06/52 – JPAC 06-29**

and

Evaluation of the effects of changes in the donor selection criterion for men who have had sex with men on the risk of transfusion-transmitted HIV in England and Wales, 2002 –2004. SACTTI 06/45 final version V9 15 May 2006 – JPAC 06-30

The JPAC paper on donor selection policy, with respect to men who have sex with other men, had been presented to MSBTO on June 20. The MSBTO Committee was not happy to accept the recommendation for “no change” on the basis of the paper as submitted. The main points made were the following:

1. The paper is focussed on HIV, and presents a quantitative estimate that a reduction to a 1-year ban would not impact the risk of HIV infection in any material way.
2. Evidence was requested evaluating the impact that a change in selection policy could have on the risk that blood recipients would be exposed to STI other than HIV.
3. UK Blood Service policy should be presented in the context of a wider consideration of the known behavioural and environmental risks of acquiring a TTI.
4. A paper had been presented to MSBTO by Liz Love and Stephen Dobra in 2004, outlining the work programme to be done, and it was important to check that the lines of work identified in this had been completed.

Action: A new paper will be sent to MSBTO for the meeting on 17th October 2006. The members of the working group producing this paper are: Pat Hewitt, Brian McClelland, David Hutton, Steven Dobra and Kate Soldan.

**PEH,
DH &
BMc**

6. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

6.1. **UK Rare Red Cell Exchange Scheme – JPAC 06-33**

Action

JPAC received a proposal from the Chair of SACIH that it could provide an oversight for the UK Rare Cell Exchange Scheme. It was agreed that this appeared to be a sensible arrangement.

Post Meeting Note

Robin Knight, co-ordinator of the scheme has agreed to prepare a short article for the JPAC web site.

6.2. Controls for high titre Anti-A/B testing of donations – JPAC 06-34

The final report on this development was approved. The new reagent will be available from Alba BioScience from the end of June, and the company will be responsible for informing Blood Services of its availability.

Action: UK Quality Managers Group to be informed: Bruce Cuthbertson.

BC**7. UKBTS FORUM UPDATE – JPAC 06-35**

MM went through the notes from the UKBTS Forum meeting on 21st April 2006. Issues relevant to JPAC were:

- Regulatory Environment
- JPAC feedback from NHSBT on report
- MSBTO
- MSM Deferral
- Prion Filtration
- vCJD Testing
- Donor Lymphocytes
- HCV NAT

8. JPAC CHAIRMANS'S REPORT**8.1. MSBTO – Report back from the meeting on 20th June 2006**

A verbal report was given by BMc as the meeting had only taken place the day before.

8.1.1. Communication

The JPAC Chair reported that he had written to Dr Rowena Jecock (MSBTO secretariat) with regard to:

- Promulgation of MSBTO advice to Tissue Banks
- Difficulties arising from sequential change notifications
- Translation of MSBTO recommendations into operational procedures and training material for staff.

The contents had been accepted by MSBTO.

8.1.2. Screening test for vCJD

MSBTO had approved the establishment of a Prion Assay Working Group to manage scientific communications with suppliers etc. This can be established as a JPAC sub-group relating to the vCJD sub-group of SACTTI.

8.1.3. Prion Filtration

Action

MSBTO received a report from the Prion Reduction Working Group. Problems had arisen with one of the candidate filter systems. The alternative system may receive CE marking before the end of the year. The proposed programme of clinical safety testing and efficacy testing was endorsed by MSBTO but issues of funding remain.

8.1.4. HCV NAT Testing

It was reported that a paper was being prepared for Ministers on this topic.

8.1.5. Plateletpheresis

NBS reported good progress on increasing the proportion of platelet concentrates collected by apheresis.

8.2. Reorganisation of JPAC – JPAC Organogram - JPAC 06-36

JPAC accepted the proposal to minimise sub committees and supported the need for further steps to improve the efficiency with which business is transacted.

8.3. Notification of changes to Quality Managers – draft memo – JPAC 06-37

JPAC approved the proposal to issue periodic briefings on the web site giving advice notice of forthcoming changes and other new information. Members were invited to notify JPAC Manager of any additions to the paper. Chair SACIH requested the addition of a note indicating that corrections/changes had been made to the Red Book.

8.4. Draft Geographical Disease Risk Index – JPAC 06-48

A report from the SACCSO Project Group was tabled for information.

9. **ANY OTHER BUSINESS**9.1. Quality Managers of the 4 UK Blood Services

BC summarised the tele conference held on 4th May. This meeting will be a forum for feeding back information to JPAC and vice versa. **Action:** The minutes will be circulated to JPAC members by CJS.

CJS

9.2. vCJD JPAC Position Statement. Version 31, 5th June 2006 – JPAC 06-39

It was pointed out that this refers to a superseded donor selection entry. **Action:** DH to update with current donor selection guideline and send to CJS to publish on the web site.

DH &
CJS9.3. Deputies for SAC Chairs at JPAC Meetings

The questions of deputies for SAC Chairs who are unable to attend JPAC meetings was raised. There was agreement that, in exceptional circumstances, it would be preferable for a deputy to attend than for the SAC to be unrepresented. However, the importance of the SAC Chair attending in person was emphasised.

The meeting closed at 15:10

Action

10. **DATE AND VENUES OF FUTURE JPAC MEETING**

2006

- Wednesday 1st November 2006 at the West End Donor Clinic in London

2007

- Thursday 1st March 2007 at the West End Donor Clinic in London
- Thursday 21st June 2007 at the West End Donor Clinic in London
- Thursday 1st November 2007 at the West End Donor Clinic in London