

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 36th Meeting held at the West End Donor Centre, London, on Wednesday 1st November 2006

Meeting commenced at 11:10 am

PRESENT

Dr Morag Ferguson	(MF)	- National Institute for Biological Standards and Control
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 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 Angela Robinson	(AER)	- Medical Director, National Blood Service
Miss Caroline J Smith	(CJS)	- JPAC Manager and minute taker

Action

1. **APOLOGIES**

Dr Bruce Cuthbertson	(BC)	- Representing the Quality Managers of the 4 UK Blood Services
Prof. Ian Franklin	(IF)	- Medical Director, Scottish National Blood Transfusion Service
Dr George Galea	(GG)	- Standing Advisory Committee on Tissues
Dr Pat Hewitt	(PEH)	- Standing Advisory Committee on Transfusion Transmitted Infections
Dr Derwood Pamphilon	(DP)	- Standing Advisory Committee on Stem Cells
Mr Stuart Penny	(SP)	- Standing Advisory Committee on Information Technology
Mr Chris Rudge	(CR)	- Medical Director, UK Transplant
Prof. Stan Urbaniak	(SU)	- Standing Advisory Committee on Immunohaematology

2. **MINUTES OF THE MEETING ON 21ST JUNE 2006**

The minutes of the last meeting were approved.

3. **MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 06-49**

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

Actions still outstanding:

§ 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 **DP**

- Action**
- 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)
- § The Chairs of SACT, SACTTI and SACSC had 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**
- § Once Chapters 22 and 24 are received, 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**
- 3.2. **Granulocytes – item 3.4.**
- BMc has asked Simon Stanworth from Oxford, along with SM & DN draft a statement for the website outlining the current JPAC position on granulocyte infusion.
- Post Meeting Note: Simon Stanworth has agreed to draft a statement together with Edwin Massey and Rebecca Cardigan.*
- 3.3. **Platelets suspended in plasma/additive solution – item 3.4.**
- Change Notification issued.
- 3.4. **Council of Europe specification for FFP – item 3.10.**
- Closed, no action required.
- 3.5. **Commonality in blood component labelling and barcoding – item 3.9.**
- SP prepared and submitted a report to the UKBTS Forum on 17th November 2006.
- 3.6. **Implementation of ISBT 128 – 3.10**
- SP is prepared and submitted a report to the UKBTS Forum on 17th November 2006.
- Information with regard to EU labelling/barcoding system for tissues, received from Dr Triona Norman at the Department of Health, has been circulated to JPAC.
- 3.7. **Summary report on component quality of red cells filtered using the Pall prion reduction device (Leukotrap® Affinity Prion Reduction Filter, LAPRF) – item 3.11.**
- DN has reopened discussions with Haemoglobinopathy Group 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:** DN will provide a short report with estimates of the likely impact on donor exposure. **DN**
- 3.8. **Briefing note on the Europack Project – 4.1.**
- This item will be taken off the “Actions List”. Once the final specifications have been discussed SM will bring back to JPAC.
- 3.9. **UK Blood Services blood component leucocyte depletion – 4.2.**
- It was agreed that SM would liaise with Dr Lorna Williamson before the next BTSAG meeting. JPAC felt it is important that this information is used correctly. **SM**

Action

3.10. **Influenza – 5.1.3.**

It was important to provide accessible information on the website outlining the main features of the UK Blood Services planning for a flu pandemic. As soon as it is available, an article prepared by Richard Bedford for Blood Matters "Pandemic Influenza and the Blood Supply", together with the recent CoE statement will be posted on the JPAC website.

Post Meeting Note: Richard Bedford article posted on JPAC website 28-12-06.

3.11. **Simian Foamy Virus – 5.1.4.**

JPAC Chair had had informal discussion (through NEPNEI) about sharing information with Human Animal Infections Risks Surveillance Group and will pursue this.

BMc

3.12. **SACTTI Working Party on Parasitology and Blood Safety Recommendations – 5.2.**

Actions from 1st June JPAC meeting still outstanding.

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

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**

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

**PEH,
DH &
BMc**

3.13. **MSM – 5.3.**

Paper submitted to MSBTO 17th October 2006 - Donor selection and testing policies to protect recipients of blood from transfusion transmissible infections (TTI).

3.14. **Controls for high titre Anti-A/B testing of donations – 6.2.**

UK Quality Managers Group informed by BC.

3.15. **Minutes of Quality Manager's Meetings – 9.1.**

Awaiting confirmed minutes to circulate to JPAC members.

BC

3.16. **vCJD JPAC Position Statement – 9.2.**

Updated with current donor selection guideline and published on the website.

4. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

4.1. **Emerging pathogens**

JPAC were asked to approve the recommendations in the risk assessments of the infectious agents:

4.1.1. **Crimean-Congo Haemorrhagic Fever – JPAC 06-50 a&b**

Endorsed by JPAC. No action required at the moment, but keep under close

surveillance. Agenda for JPAC meeting 1 st November 2007.	<u>Action</u>
In discussion it was noted that the responsibility for the surveillance of new information about new and emerging infections must be clarified, and appropriate resources must be found for this activity. Action BMc and PEH.	BMc & PEH
4.1.2. <u>Dengue</u> – JPAC 06-51	
Endorsed by JPAC. No action required at the moment, but keep under close surveillance. Agenda for JPAC meeting 1 st November 2007 and check with SACTTI to see if we have a review of international donor selection practice in relation to Dengue.	
DH to send PEH information he has on Dengue to update the risk assessment.	DH
4.1.3. <u>Simian Foamy Virus</u> – JPAC 06-52 a&b	
It was noted that Health Canada had introduced a donor exclusion for individuals who had occupational exposure to primates. It was decided that (1) this should be kept under review (2) no additional donor exclusion criteria should be introduced at this time (3) the organisations that employ individuals that work with primates should be contacted with a view to informing such employees that they should not donate blood or tissues.	
<i>Post Meeting Note: Chair of JPAC has reviewed this decision and written to SACTTI Chair to request reconsideration including review of all relevant papers from Health Canada, FDA and Republic of Ireland.</i>	
4.1.4. <u>Human Herpesvirus-8</u> – JPAC 06-53 a&b	
No action required at the moment, but keep under close surveillance. Agenda for JPAC meeting 1 st November 2007. Action Chair JPAC and SACTTI review the SACTTI paper and other relevant evidence.	PEH & BMc
4.2. <u>SACTTI discussion paper on policies to reduce transfusion-transmitted HBV - JPAC 06-54a and Additional information paper JPAC 06-54b</u>	
It was evident that despite all the new data, this is a topic on which SACTTI and JPAC continue to have difficulties in framing a recommendation. Chair of JPAC suggested that before attempting to prepare a submission for MSBTO an opinion should be sought from the DH group on Hepatitis. JPAC agreed this proposal. Action BMc and PEH.	PEH & BMc
There was extensive discussion, mainly concerning the general issue of how much resource should be committed to reducing a risk when all the evidence seems to suggest that it is extremely small. It was suggested by one member that this is a simple issue of cost benefit – if one can confidently estimate that there would be (for example) 5 transmissions per year and that an intervention could reduce this to 2 cases per year, how would the economic and other considerations be weighed in making a decision?	
It was noted by several members that there appears to be no consensus about the acceptability of any level of risk, or the level of resources that should reasonably be committed to a given level of reduction.	
The view was expressed by one member that if blood was a market commodity there would be no question that all available safety tests would be carried out.	
It was also stated that blood components tested by PCR for a wide range of viruses was already available from at least one EU country at relatively low cost.	

Action

It was suggested that there are parallels with the risk benefit assessments that have to be made about vaccines and that there maybe a useful body of experience in that field that could be drawn on. Action BMc to discuss with SI.

BMc**5. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS****5.1. Stability of coagulation factors in methylene blue 9MB) treated fresh frozen plasma once thawed – JPAC 06-55**

JPAC endorsed the recommendation that a change in the allowable post-thaw storage time of Methylene Blue (MB) FFP to 24 hours if stored at 4°C, consistent with that of standard FFP.

JPAC however expressed interest in the ETP (Endogenous Thrombin Potential) figures at 48 and 72 hours for which there appeared to be striking differences between FFP and MB FFP and suggested that this would merit some further investigation. Action SM

SM**6. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS****6.1. Disability Discrimination Act (DDA): discussion paper (BMc) – JPAC 06-56**

The DDA has an extension which comes into force on 4th December 2006 for public bodies.

There are two issues:

- (1) donors with a disability
- (2) donors who require an interpreter.

There was extensive discussion about the implications of using third party interpreters. There was general agreement that if third party interpreters are required for any part of the donor selection process which may require the exchange of confidential information between the donor and the qualified health professional, then the interpreter must be familiar with the relevant aspects of the blood safety and quality regulations and understand the importance of obtaining correct information and of safeguarding the donors confidentiality.

Post Meeting Note: Donor selection guidelines adopting this approach have now been approved by the UKBTS Forum (17th November 2006) and Change Notifications were issued on 13th December 2006. Legal advice will be obtained on the precise wording of the DSG in relation to the various pieces of legislation that touch on this.

7. UKBTS FORUM UPDATE – JPAC 06-57

MM went through the notes from the UKBTS Forum meeting on 28th July 2006.

Issues relevant to JPAC were:

- Prion Filtration – outcome exploring whether a legal opinion should be sought. MSBTO said yes and supported funding.
- vCJD Testing – established Prion Assay Working Group – donor issues should be taken into account.

Action

8. **HEALTH PROTECTION AGENCY (HPA)**
- HPA Consultation**
- The question was raised as to whether JPAC should respond to this consultation. It was decided that each Service should reply and that a response from the Prion Assay Working Group would be important.
9. **JPAC CHAIRMANS'S REPORT**
- 9.1. **Deputy Chair of JPAC**
- BMc informed JPAC that SM had agreed to take on the role of Deputy Chair of JPAC.
- 9.2. **MSBTO**
- 9.2.1. **"Donor selection and testing policies to protect recipients of blood from transfusion transmissible infections (TTI)"**
- BMc had presented an updated paper on "Donor selection and testing policies to protect recipients of blood from transfusion transmissible infections (TTI)" to the MSBTO meeting on 17th October 2006.
- There has also been discussion with Professor Kaye Wellings (LSHTM) and a representative of DH to develop a proposal for a research study to investigate the likely effect of a change in donor exclusion regulations on donor's compliance with the regulations.
- It was noted by MSBTO that the present paper does not appear to explain adequately the basis for a life time exclusion for MSM, in comparison with a one year deferral for donors reporting sexual contacts from sub Saharan Africa. Also that the final position statement should balance the behavioural risks in the heterosexual population with those in the MSM group.
- MSBTO had agreed that there was no evidence that persuades its members of a need to change current policy, that more work is needed to develop a position statement and there is a need to develop a research proposal as above.
- 9.2.2. **MSBTO – risks of vCJD transmission from donated bone and tissues**
- The Chair of JPAC reported that MSBTO had further considered, at its meeting on 17th October, the details of donor exclusions to be recommended to apply to donated bones and tissues. The Chair proposed that JPAC should await the final agreed record of the MSBTO decisions before taking action to prepare and issue revisions to the relevant donor selection guidelines. **BMc**
- 9.3. **EAGA Meeting 18th October 2006**
- The Chair of JPAC briefly presented some key points of the October meeting of EAGA and will circulate a brief report in due course. **BMc**
- 9.4. **NEPNEI**
- The Chair of JPAC will attend the forthcoming meeting of NEPNEI on 6th December and will provide a brief report for JPAC from that meeting. **BMc**
- 9.5. **JPAC Website**

Action

BMc informed JPAC that there will be a new section in the JPAC website for the National Transfusion Committee and this will be edited by Sheena Cameron who is based in Oxford NBS Centre.

9.6. **Council of Europe**

It was reported that the Council of Europe's activities, relating to blood transfusion, will shortly be transferred into the European Directorate for the Quality of Medicines. This Directorate produces the European Pharmacopoeia in co-operation with the European Commission.

Further information about the precise terms of reference etc. governing this new arrangement are due to be released before the end of 2006.

The Chair suggested that this might open up somewhat different possibilities for JPAC to contribute to changes and improvements in the CoE guidelines and may also provide a route for communicating proposed changes to the EU Directives. With respect to the latter, SAC Chairs are asked to send a brief note to CJS indicating their SACs top priorities for changes in the Directives.

**SAC
Chairs**

The meeting closed at 15:02

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