

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 31st Meeting held at West End Donor Centre, London, on Wednesday 23rd February 2005

Meeting commenced at 10:30 am

PRESENT

Dr Frank Boulton	(FB)	-	Standing Advisory Committee on Care and Selection of Donors
Dr Morag Ferguson	(MF)	-	National Institute for Biological Standards and Control
Dr George Galea	(GG)	-	Standing Advisory Committee on Tissues and Stem Cells
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)	-	Chair of JPAC and the Standing Advisory Committee on Clinical Transfusion Medicine
Dr Morris McClelland	(MM)	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Willie Murphy	(WM)	-	National Medical Director, Irish Blood Transfusion Service
Prof. Stan Urbaniak	(SU)	-	Standing Advisory Committee on Immunohaematology
Miss Caroline J Smith	(CJS)	-	JPAC Office Manager (Minute taker)

Please note the meeting, and therefore these minutes, do not follow the order of the agenda.

Action

1. **APOLOGIES**

Mr Paul Ashford	(PA)	-	Standing Advisory Committee on Information Technology
Dr Bruce Cuthbertson	(BC)	-	Standing Advisory Committee on Plasma for Fractionation
Prof. Ian Franklin	(IF)	-	Medical Director, Scottish National Blood Transfusion Service
Dr Stephen Inglis	(SI)	-	Director, National Institute for Biological Standards and Control
Ms Barbara Morris	(BM)	-	Medicines and Healthcare Products Regulatory Agency
Dr Angela Robinson	(AER)	-	Medical Director, National Blood Service
Mr Chris Rudge	(CR)	-	Medical Director, UK Transplant

2. **MINUTES OF THE MEETING ON 10TH NOVEMBER 2004**

The minutes of the last meeting were approved.

3. **UK FORUM UPDATES – JPAC 05/02**

Morris McClelland went through his report JPAC 05/02.

BMc will now attend every UK Forum meeting in his capacity as Professional Director of JPAC.

It was agreed that JPAC and SAC minutes will appear in the "Document Library" on the JPAC web site transfusionguidelines.org.uk, which is open to the general public.

Action

4. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS**
- 4.1. **Draft - Shelf life of red cells in additive solution (SAG-M) – JPAC 05/04**
- JPAC endorsed the recommendations in this document in principle. SACBC was asked to update the recommendations with information on which other countries have a shelf life of 42 days for red cells in additive solution. The JPAC Chair will then take these recommendations to the next UK Forum meeting in May 2005. **SM & BMc**
- This information should also appear in the new edition of the Red Book. **SM**
- 4.2. **Deviations from 4°C temperature storage for red cells – effect on viability and bacterial growth – JPAC 05/05**
- The recommendations in this document were discussed at length. The JPAC Chair asked SACBC to update the recommendations with JPAC comments and send to CJS for circulation to JPAC members for final comments. The JPAC Chair will then take these recommendations to the next UK Forum meeting in May 2005. **SM & CJS**
BMc
- 4.3. **Specifications for buffy coats**
- There is no specification for buffy coats in the current Red Book. Since there are no data on the efficacy or effectiveness of this product JPAC agreed that a specification relating to efficacy would not be meaningful. It was agreed, however, that there should be a description in the Red Book of current products and a specification of characteristics related to product safety.
- SACBC to draft a product description with safety requirements for buffy coats and send to CJS for circulation to JPAC. **SM & CJS**
- 4.4. **SACBC summary of activity for 2004 and workplan for 2005 – JPAC 05/06**
- Circulated to JPAC for information. All SAC work plans and forward looks will be reviewed at the next JPAC Executive Working Group Meeting. **ALL**
5. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION**
- 5.1. **Deferral for blood donors recently immunised with vaccines – JPAC 05/07**
- SACTTI asked JPAC to accept this as the final paper. JPAC accepted this paper and endorsed its recommendations. The JPAC Chair will take these recommendations to the next UK Forum meeting in May 2005. **BMc**
- 1) **Routine immunisations**
It is recommended that the period of donor deferral after immunisation with any live attenuated vaccine should be extended to 8 weeks
 - 2) **Temporary derogation of deferral periods**
In the situation of large-scale vaccination infectious risks to recipients from viraemic blood donations must be balanced against the need to maintain adequate blood component supplies. Under these circumstances a temporary derogation of deferral period to 21 days is suggested. In certain situations this may be reduced still further for selected donors. Such donations should be used

Action

only where absolutely necessary.

Recommendation 1 needs to include relevant actions which apply to tissues.
The JPAC Chair asked GG to draft a paragraph and send to BMC/CJS.

GG

5.2. **Creutzfeldt-Jakob Disease: Position Statement, version 28, 25th January 2005 – JPAC 05/08**

JPAC approved this latest position statement. CJS will send to Serge Six for publication on the JPAC web site transfusionguidelines.org.uk.

Post Meeting Note: Posted on the web site transfusionguidelines.org.uk 1st March 2005.

The need for this Position Statement to carry an expiry date was discussed. JPAC concluded that this is part of the larger issue of periodic review and updating of content. This needs to be pursued by JPAC, but in the meantime expiry dates will not be added. Action: CJS to put on the agenda for the November JPAC meeting.

CJS

5.3. **West Nile Virus: Position Statement, version 5, 8th December 2005 – JPAC 05/09**

JPAC approved the content of this document. The amendments to deferral criteria will be issued as a Change Notification in the normal way and concurrently the revised Position Statement will be published on the web site.

LL &
BMc

5.4. **Notes on Joint SACTTI/SACCSA Ad Hoc Group – West Nile Virus and Avian Flu, 8th December 2004 – JPAC 05/10**

The JPAC Chair sought advice from JPAC on the need for any action specifically related to donor selection in the event of an outbreak of Avian Flu in the UK. It was reported that this specific issue is not referred to in the Governments Influenza Pandemic Contingency Plan* the draft of which JPAC has not had access to.

AER had asked Roger Eglin and the Chair of SACTTI to comment on the plan and these comments had been fed back to the NEPNEI. The Chair of SACTTI was asked to forward this information to the JPAC Office as a record.

Members advised that there is not a period of viraemia prior to the appearance of symptoms of Avian Flu and that therefore there is no indication of any specific donor measures such as those that had been introduced as a precaution during the SARS outbreak.

Post Meeting Note: Are there any donor selection issues related to possible widespread use of antiviral drugs? SACCSA to investigate.

FB

* This document has now been published, version 7.0/February 2005 (<http://www.dh.gov.uk/assetRoot/04/10/44/37/04104437.pdf>), as has the HPA plan.

5.5. **Response of the SACTTI Advisory Group on Blood Parasites to the EU Blood Directive rules for the deferral of malaria risk donors, final version, 8th December 2004 – JPAC 05/11**

Circulated for information only. The JPAC Chair took this paper to the Council of Europe SP-GS Drafting Group meeting held in Uppsala, Sweden on 1st to 4th February 2005.

BMc to send CJS documents prepared by Australia and the draft of the next CoE guide which will then be sent to SACTTI and SACCSA.

BMc &
CJS

	<u>Action</u>
5.6. <u>Proposed Red Book standards for arm cleansing and monitoring, diversion and bacterial detection, final version, 2nd February 2005 – JPAC 05/12</u>	
Recommendations 1, 2, and 3 were approved by JPAC and will appear in the next edition of the Red Book. JPAC recommended that the word “shall” be replaced with the word “should”.	LL
Recommendation 4 (measures of detecting contamination of platelets concentrates). It was agreed that in view of the substantial resource implications this would be conveyed to the UK Forum May meeting by the Chair of JPAC.	BMc
5.7. <u>Microbiology testing for tissue and stem cell donors (Phil Yates summary paper)</u>	
This paper is progressing and will be discussed again on 8 th March and then taken to the SACTTI meeting on 22 nd March for their endorsement. LL will then send to CJS to circulate to JPAC with a short deadline for final comments.	LL & CJS
5.8. <u>Prion Removal</u>	
LL asked JPAC to approve the following papers:	
5.8.1. <u>Validation of red cell and plasma quality following Prion Removal (S132) – JPAC 05/13</u>	
JPAC approved this paper as an evaluation protocol. The Chair of JPAC will write to Dr Lorna Williamson, Chair of the Prion Removal Group, to convey this approval.	BMc & CJS
5.8.2. <u>SACTTI vCJD Working Group – Validation of efficacy of prion removal filters – JPAC 05/14</u>	
JPAC approved this paper in principle, but recommends that it is referred to SEAC (Spongiform Encephalopathy Advisory Committee) as it was felt that the JPAC members present did not have the expertise to review this critically. The Chair of JPAC write to Dr Lorna Williamson to convey JPACs comments.	BMc & CJS
5.8.3. <u>Prion Removal Working Group – Prion removal devices: Interim operational specification – JPAC 05/15</u>	
JPAC approved this paper. In view of the small number of attendees at this JPAC meeting the JPAC Chair asked for any further comments to be sent to CJS to send to Dr Lorna Williamson. The Chair of JPAC will write to Dr Lorna Williamson to convey this approval.	BMc & CJS
5.9. <u>Malaria rules: Changes in geographical risk in relation to the Tsunami 26-12-04 disaster zone – JPAC 05/31</u>	
JPAC approved this as a Change Notification”. The JPAC Office will issue the Change Notification week beginning 7 th March 2005.	BMc & CJS
6. <u>STANDING ADVISORY COMMITTEE ON TISSUES AND STEM CELLS</u>	
6.1. <u>MSBT – Summary of committee/decisions / advice from the meeting held on 20th January 2005 – JPAC 05/16</u>	
Circulated for information.	

Action6.2. **The EU Tissues and Cells Directive – Essential Guidance (version 3. 17-12-2004) – update from Policy Collaborative – JPAC 05/18**

The above paper arose from the Department of Health Policy Collaborative and had been sent to JPAC for information.

A pilot study will take place in England in 7 Trusts. The guidelines will be issued to various categories of people to assess their knowledge of the Tissues Directive. Based on the findings of this pilot a full release of the guidelines is planned for July/August 2005.

The main purpose of this is to ensure that hospitals are made aware of the impact the Tissues Directive may have on their activities.

It is likely Scotland will follow suit, issuing the same guidelines with a separate covering letter.

6.3. **Warning labels – tissue products – JPAC 05/19**

Circulated for information.

7. **STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**7.1. **Donor Haemoglobin Testing**

DSG will be changed in line with the EU Regulations.

7.2. **Donor Selection Criteria – item 4.4. from last JPAC meeting on 10th November 2004**

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|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| 1. | Prepare a report for JPAC of the work to date on the review of evidenced based donor selection guidelines – not yet received. | FB |
| 2. | Include a recommendation as to what additional work is required and how it should be undertaken – not yet received. | FB |
| 3. | Produce a note of the issues that, in the opinion of the SACCS, need to be taken to the next Council of Europe meeting (Uppsala, Sweden, 1 st to 4 th February 2005) on behalf of the UK with a view to future changes in the guide and then the Directive – not received. | FB |

7.3. **Acupuncture – item 15.1. from last JPAC meeting on 10th November 2004**

FB to send "Change Notification" to CJS – still outstanding

FB

7.4. **Re-appraisal of the donor age criteria for the UK – item 15.3. from last JPAC meeting**

FB will send the new paper to CJS – still outstanding

FB

7.5. **Gay men and blood donation**

JPAC noted that frequent enquiries continued to be received concerning the basis for current donor selection criteria. It was therefore agreed that SACCS would prepare a position paper which may include the epidemiology report by Katy Davison, NBS/HPA Surveillance, May 2004.

FB

Action**8. MATTERS ARISING NOT ON THE AGENDA (review of actions list) JPAC 05/01**

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

8.1. Framework for evaluation of pathogen reduction of blood components – item 4.3.

CJS to organise a teleconference between BMc, LL and SM to decide how to take this forward in conjunction with the Prion Reduction Filter Working Group's work.

CJS

8.2. RhD Grouping of Plasma – item 4.11.

Work in progress.

SU

8.3. High Titre Anti-A/B Testing – item 4.12.

Work in progress – results in due course.

SU

8.4. Notification of Change – item 9.

New Change Notification ready for use.

8.5. Policy on emerging infections – item 11.2.

LL to send the final version of this paper, which is being discussed at the next SACTTI meeting on 22nd March 2005, to CJS for the next JPAC meeting in June.

LL

8.6. Calculated microbial risk from blood transfusion – item 12.2.

A summary paper for the public web site is still required – action BMc and LL. Risk information relevant to recipient of tissue transplants is also required. A specification of the information needed is to be prepared by SACTSC.

LL,
BMc &
GG**8.7. Increasing volume of blood collected to 500 ml plus samples – item 15.1.**

JPAC agreed that this must be taken as part of the wider review of the haematological effects of blood donation.

8.8. Update on upper limit of pH – item 16.4.

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

SM

9. EUROPEAN UNION BLOOD DIRECTIVE (2002/98/EC)/ THE BLOOD SAFETY AND QUALITY REGULATIONS 2005

These regulations were discussed in detail at the JPAC Executive Working Group meeting held on 14th March 2005.

9.1. Labelling of blood and blood components and traceability

BMc read out the following minute from the JPAC Executive Working Group minutes of the meeting held on 14th March 2005.

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"BMc stated that all the indications are that MHRA will require compliance with the regulations.

SM stated that in some cases, where there is a large amount of information on the label, putting the word "leucodepleted" in full would mean that the text would be too small to read. SM suggested as a compromise we use "LD" to represent Leucodepleted – to be used consistently on all component labels. This was agreed and will be put to JPAC".

JPAC accepted the suggested abbreviation of "LD", but advised that the MHRA should be consulted in view of the fact that the MHRA member of JPAC had been unable to attend this meeting. The Chair of JPAC will write to Barbara Morris the JPAC MHRA representative.

BMc

9.2. **Leucocyte content**

JPAC noted that the current Red Book states: "The UK specification for leucodepletion is that a minimum of 99% of leucocyte depleted components from relevant processes should have less than 5×10^6 leucocytes with 95% confidence". Where as the Blood Safety and Quality Regulations 2005 states a specification of " $<1 \times 10^{6n}$ " with no indication of sampling schedule etc. It was agreed that SACBC would provide, for the June JPAC meeting, a summary of the UK Blood Services leucodepletion performance data to enable an assessment of compliance.

SM

10. **7th EDITION OF THE RED BOOK – UPDATE**

The deadline for any outstanding chapters is now the end of February 2005. This deadline must be met if we are to publish by June/July 2005, which is felt to be the latest acceptable date.

11. **STANDING ADVISORY COMMITTEES**

At the JPAC Executive Working Group meeting on 14th March it was agreed that a meeting/workshop should be arranged to discuss the role and internal/external relationships of the JPAC SACs. Participants would be the Chair of JPAC, the SAC Chairs and an external expert facilitator, possibly someone from ESOR who has already worked on this with LL (Steven Dobra).

Post meeting note

This meeting will take place on Thursday 16th June 2005 at the West End Donor Centre in London.

12. **WEB SITE REPORT – JPAC 05/03**12.1. **Web Site User Groups**

The first meetings of the User Groups are due to take place in early March 2005.

Post Meeting Note

*Whole Blood & Apheresis User Group – 4th March 2005 (facilitated by Serge Six)
Tissue Donor Selection Guidelines User Group – 7th March (facilitated by Yvonne Elliot)*

Action

12.2. **Relaunch of web site**

The web site transfusionguidelines.org.uk will be relaunched on 28th February 2005. It has been expanded to include the new areas - DoH Better Blood Transfusion Toolkit, the Operational Impact Working Group and the UK Blood Services Systematic Review Initiative, along with the new search facility.

The JPAC Chair asked members to review the list of systematic reviews and invited members to propose topics for further systematic reviews.

12.3. **Review of hosting arrangements – JPAC 05/03**

Due to the expansion of the web site the hosting facilities will need to be enhanced. This can be achieved with our current provider, but will not provide any additional facilities or expert support and would cost approximately £40,000. Therefore the possibility of finding an alternative provider has been researched

SHOW, Scottish Health On the Web, has been identified as one possible provider who appears to offer substantial advantages in the quality of facilities etc.

JPAC gave its support for a review of the hosting arrangements of the web site.

13. **ANY OTHER BUSINESS**

No items were raised.

The meeting closed at 15:15

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

- Wednesday 22nd June 2005 at the West End Donor Centre in London
- Wednesday 26th October at the West End Donor Centre in London