

# Joint UKBTS/NIBSC Professional Advisory Committee

## Minutes of the 30<sup>th</sup> Meeting held at British Medical Association, BMA House, Tavistock Square, London on Wednesday 10<sup>th</sup> November 2004

Meeting commenced at 10:30 am

### PRESENT

Dr Frank Boulton	<b>(FB)</b>	-	Standing Advisory Committee on Care and Selection of Donors
Dr Bruce Cuthbertson	<b>(BC)</b>	-	Standing Advisory Committee on Plasma for Fractionation
Dr Morag Ferguson	<b>(MF)</b>	-	National Institute for Biological Standards and Control
Dr George Galea	<b>(GG)</b>	-	Standing Advisory Committee on Tissues and Stem Cells
Dr Richard Jones	<b>(RJ)</b>	-	Medical Director, Welsh Blood Service
Dr Liz Love	<b>(LL)</b>	-	Standing Advisory Committee on Transfusion Transmitted Infection
Dr Sheila MacLennan	<b>(SM)</b>	-	Standing Advisory Committee on Blood Components
Dr Brian McClelland	<b>(BMc)</b>	-	<b>Chair of JPAC</b> and the Standing Advisory Committee on Clinical Transfusion Medicine
Dr Morris McClelland	<b>(MM)</b>	-	Medical Director, Northern Ireland Blood Transfusion Service
Ms Barbara Morris	<b>(BM)</b>	-	Medicines and Healthcare Products Regulatory Agency
Dr Angela Robinson	<b>(AER)</b>	-	Medical Director, National Blood Service
Prof. Stan Urbaniak	<b>(SU)</b>	-	Standing Advisory Committee on Immunohaematology
Miss Caroline J Smith	<b>(CJS)</b>	-	JPAC Office Manager ( <b>Minute taker</b> )

BMc welcomed Barbara Morris, MHRA Representative, to her first JPAC meeting.

### Action

#### 1. **APOLOGIES**

Mr Paul Ashford	<b>(PA)</b>	-	Standing Advisory Committee on Information Technology
Prof. Ian Franklin	<b>(IF)</b>	-	Medical Director, Scottish National Blood Transfusion Service
Dr Stephen Inglis	<b>(SI)</b>	-	Director, National Institute for Biological Standards and Control
Dr Willie Murphy	<b>(WM)</b>	-	National Medical Director, Irish Blood Transfusion Service
Mr Chris Rudge	<b>(CR)</b>	-	Medical Director, UK Transplant

#### 2. **EUROPEAN UNION BLOOD DIRECTIVE (2002/98/EC)**

The first part of this JPAC meeting was taken up discussing the European Union Blood Directive 2002/98/EC and its transition into UK Law.

AER informed JPAC that the new edition of the NBS Blood Matters (issue 16, Autumn 2004) contained articles on the European Blood Directives and Role of the European Blood Directive NHS Operational Impact Working Group. Hard copies are due to be circulated to hospitals covered by the NBS the week beginning 22<sup>nd</sup> November 2004.

*Post meeting note: PDF version of Blood Matters, issue 16, circulated by CJS 11/11/04.*

##### 2.1. **Summary of position**

**Action**

**Public consultation on the blood safety and quality regulations 2005**

Launch date 12<sup>th</sup> November 2004. Closing date 8<sup>th</sup> January 2005. This consultation asks for comments on proposed regulations imposing safety and quality requirements on human blood collection, testing processing and storage.

*Post meeting note: Consultation letter and relevant documents downloaded from DH web site and circulated to JPAC and Joan Jones 12/11/04 by CJS.*

Transitional Provision – Regulation comes into force on 8<sup>th</sup> February 2005. UK intends to take advantage of Regulation 23 – maintain existing national provisions for 9 months (until 8<sup>th</sup> November 2005).

AER informed JPAC that the 4 UK Blood Services will respond to the consultation in a united manner. AER and BMC will co-ordinate the JPAC response, which will then go to the UK Forum.

**Actions to ensure a co-ordinated response by the 4 UK Blood Services:**

Members are asked to provide the responses required in the following table by the extended deadline of Friday 10<sup>th</sup> December 2004. JPAC response will then be sent to the UK Forum to approve in time for the 8<sup>th</sup> January 2005 deadline.

## Public Consultation on The Blood Safety and Quality Regulations 2005

Response to specific questions raised in the Consultation letter from Richard Gutowski (Gateway No.: 3998, 11<sup>th</sup> November 2004)

Regulation	Subject	Summary question	Action required and by whom
Regulation 7 (1)(j) (Article 19 of directive)  <b>Page 18</b>	<b>Healthcare Professionals</b>	It may be necessary to provide a definition of 'a qualified health professional' specific to these regulation in order to encompass current practice. Suggestions are invited on the format of that definition. We are considering issues related to the inclusion of Donor Carers in that definition (Paragraph 11)	<a href="#"><u>Angela Robinson</u></a>  <i>Provide the appropriate definition of a Healthcare Professional.</i>
Regulation 7 (1)(h) Schedule to the regulations Part 3, paragraph 1.2.  <b>Page 18</b>	<b>Haemoglobin levels</b>	Your comments are invited on this potential impact and whether the 'exceptional circumstances' derogation in Part 3 of the schedule to the regulations is a practical solution to this issue. (Paragraph 11)	<a href="#"><u>Frank Boulton (Chair of SACCS D)</u></a>  <i>Provide a specific recommendation on Hb levels at which male and female donors can be accepted, stating testing and sampling methods etc., which can be given in the UK Donor Selection Guidelines.</i>
Regulation 7 (1)(h) Schedule to the regulations Part 3, paragraph 2.2.1.  <b>Page 20</b>	<b>Malaria</b>	Current UK guidelines in respect of malaria use different definitions and deferral periods and your comments are invited on this issue. (Paragraph 11)	<a href="#"><u>Frank Boulton (Chair of SACCS D and Liz Love (Chair of SACTTI)</u></a>  <i>Provide a joint statement specifying the deferral criteria to be given in the UK Donor Selection Guidelines.</i>
Regulation 8 (1)(a) Schedule to the regulations Part 5, paragraph 1  <b>Page 22</b>	<b>Labelling of products</b>	In the UK, as all components are leucocyte depleted, current labelling arrangements do not specify leucocyte-depletion and your comments are invited. (Paragraph 11). A decision is also needed on the anticoagulant details on the label.	<a href="#"><u>Sheila MacLennan (Chair of SACBC) and Bruce Cuthbertson (Chair of SACPF)</u></a>  <i>Provide a recommendation on whether or not any changes to the current UK blood component labels are required and specifying any such changes.</i>
Regulation 4 (9) and (10)	<b>Substantial changes</b>	Your comments are invited on the definition.	<a href="#"><u>All JPAC Members</u></a>

Regulation	Subject	Summary question	Action required and by whom
esp. 10(c) <i>Page 4</i>	<b>(Authorisation of a Blood Establishment)</b>	(Paragraph 11)	<i>Provide a definition of “substantial changes” with one or two examples, or state if you feel the definitions in 10 (a to c) are sufficient.</i>
Regulations 9 – 10 <i>Page 8</i>	<b>Hospital Blood Banks</b>	I would welcome your comments on the impact of the regulations on hospital blood banks and the potential costs of implementation. (Paragraph 12)	<b>Response requested from:</b> <i>1. Operational Impact Group (Joan Jones)</i> <i>2. JPAC Members if they wish to comment</i>
Regulation 13 (5)(a) <i>Page 10</i>	<b>Hospital Blood Bank compliance</b>	The Competent Authority will decide what if any system is needed to obtain such assurance and your comments are invited on the extent and format of such systems. (Paragraph 18)	<b>Response requested from:</b> <i>1. Operational Impact Group (Joan Jones)</i> <i>2. JPAC Members if they wish to comment</i>
Regulatory Impact Assessment (RIA)		Comments are invited on the potential non-recurring (i.e. start-up) costs and recurring costs of complying with the legislation, such information will be particularly welcome from the private sector institutions affected by the regulations. (Paragraph 21)	<b><u>All JPAC Members &amp; Operational Impact Group</u></b> <i>JPAC and Operational Impact Group members are asked to comment – in particular on:</i> <i>1. Page 1, 2.4 (c) Comment on the cost and feasibility of complying with “All blood donations (whole blood and blood components) will have to be traceable from “vein to vein” i.e. from donor to patient”.</i> <i>2. Impact on availability of donations of compliance with Hb criteria.</i> <i>3. Cost and other risks of changing blood component labels.</i> <i>4. Additional inspection and local audit costs.</i> <i>5. 30 year storage costs.</i>

<b>Other Issues Identified by JPAC</b>			
<b>Regulation</b>	<b>Subject</b>	<b>Action required and by whom</b>	
Part 5 <i>Page 22</i>	<b>List of Blood Components</b>	<i>JPAC concluded that this list is not intended to be exhaustive.</i>	
Part 3, 2.2.1. <i>Page 20</i>	<b>“Fever” &gt;°C</b>	<u><a href="#">Frank Boulton (Chair of SACCS D) and Liz Love (Chair of SACTTI)</a></u>  <i>Confirm that this will be interpreted as fever reported by the donor.</i>	
Part 3, 2.2.2. <i>Page 20</i>	<b>Endoscopy</b> – Endoscopic examination using flexible instruments	<u><a href="#">Frank Boulton (Chair of SACCS D) and Liz Love (Chair of SACTTI)</a></u>  <i>Provide a specific recommendation as to how “endoscopic ………” is to be interpreted by Donor Operational Teams. (Accept proposed deferral criteria)</i>	
Part 3, 2.2.2. <i>Page 20</i>	<b>Major Surgery</b>	<u><a href="#">Frank Boulton (Chair of SACCS D) and Liz Love (Chair of SACTTI)</a></u>  <i>Provide a specific recommendation as to how “major surgery” is to be interpreted by Donor Operational Teams. (Accept proposed deferral criteria)</i>	
Part 3, 2.2.4. <i>Page 21</i>	<b>Pregnancy</b>	<u><a href="#">Frank Boulton (Chair of SACCS D)</a></u>  <i>Provide a specific recommendation interpreting this paragraph to take sensible account of early termination in a form that is useable by Donor Operational Teams</i>	
	<b>Plasma for Fractionation</b>	<u><a href="#">Bruce Cuthbertson (Chair of SACPF F)</a></u>  <i>Provide a recommendation of the criteria for plasma for fractionation.</i>	

2.2. **Recommendations from SACTTI/SACCSD Meeting**

Recommendations/actions from this meeting are covered in item 2.1.

2.3. **Donor Haemoglobin testing**

SACCSD recommends the EU specified donor Hb levels of 12.5/13.5. Estimate by Dr E Caffrey is that 25,000 donors/year will be lost across the UK.

3. **MINUTES OF THE MEETING ON 17<sup>th</sup> JUNE 2004**

The minutes of the last meeting were approved.

4. **MATTERS ARISING NOT ON THE AGENDA (review of actions list) JPAC 04/50**

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

4.1. **Safety of Blood Leaflets – item 4.1.**

Inclusion of HTLV positive donors in deferral criteria. This change will be made during the next print run. Closed to JPAC

4.2. **Website – Link to Blood Conservation Strategy – item 4.6.**

This strategy is back with the Appropriate Use of Blood Group. Closed to JPAC.

4.3. **Framework for evaluation of pathogen reduction of blood components - item 4.9.**

A teleconference will be organised between BMc, LL and SM to decide how to take this forward in conjunction with the Prion Reduction Filter Working Group's work.

CJS

4.4. **Donor Selection Criteria – Evidence Base – item 4.13.**

FB reported that this work was progressing and is described in the draft minutes of the SACCSD meeting on 1<sup>st</sup> October and the minutes for the May SACCSD meeting.

**Actions for FB Chair of SACCSD**

FB

1. Prepare a report for JPAC of the work to date on the review of evidenced based donor selection guidelines.
2. Include a recommendation as to what additional work is required and how it should be undertaken.
3. Produce a note of the issues that, in the opinion of the SACCSD, need to be taken to the next Council of Europe meeting on behalf of the UK with a view to future changes in the guide and then the Directive.

4.5. **Autologous Labelling – item 4.14.**

Document received and circulated to JPAC members 23<sup>rd</sup> July 2004. Closed

4.6. **I/v fibrinogen – contact at MHRA – item 14.16.**

BMc wrote to Dr Joyce Lawrence at the MHRA in July. CJS was informed in October that Dr Lawrence had sent this letter to Dr Carol Penning for a MHRA response. Closed to JPAC

4.7. **JPAC Annual Report – item 5.**

The JPAC Annual Report and BMC's addendum circulated to JPAC 21<sup>st</sup> June 2004. Closed

4.8. **Freedom of Information Act – item 6.2.2.**

CJS to write to AER asking if JPAC papers should appear on the NBS publication scheme with copies to the Medical Directors of the other 3 Services.

**CJS**

4.9. **Chairs of SACIT and SACCTM – item 6.3.**

No further information received.

4.10 **EU Regulatory Committees – item 7.**

Paper explaining the EU Directives and Committees etc. by WM circulated to JPAC 25<sup>th</sup> October 2004. Closed

4.11. **RhD Grouping of Plasma – item 8.3.**

Work in progress

**SM**

4.12. **High Titre Anti-A/B Testing – item 8.4.**

SU had submitted papers JPAC 04/79 and 04/80 and asked JPAC to send him any comments. This would be discussed again at the next JPAC meeting in February 2005.

**SU &  
CJS**

4.13 **Donor/patient consent to provide materials for reagents – item 11.**

SU informed JPAC that this issue had been discussed extensively by the SAC-IH and their conclusions were:

Existing procedures for donor consent in the UK Blood Services were sufficient for obtaining red cells, plasma and probably DNA for current testing procedures (e.g. already archived for microbiology) and would be referred to in the appropriate section of the Red Book.

For patients, and possibly for donors also we felt we needed to await the final requirements of the Human Tissues Act which is currently still with Parliament. For the purposes of the Red Book, we are inclined to just refer to "compliance with the HTA".

4.14. **SACIT Recommendation on the Rollout of ISBT 128 – item 12.3.**

This was discussed at the UK Forum on 30<sup>th</sup> July 2004. BMC will ask the UK Forum for an update for the next JPAC meeting in February 2005.

**BMc**

4.15. **EOR (Economics and Operational Research) papers – item 14.1.**

LL sent two papers to CJS for circulation to JPAC. These papers are **not** for further dissemination.

1. vCJD infection risks of bone products: A comparative assessment (BONE 3.doc)
2. On the risk of vCJD transmission via donated tissues or stem cells: Preliminary analysis (paper 1-0.doc).

Closed.

4.16. **Council of Europe – Relationship with SACTSC – Item 14.3.**

Rachel Green, UK Representative for Tissues, has become a member of SACTSC.

Closed.

4.17. **Microbiology testing for tissue and stem cells donors (Summary paper by Phil Yates – Item 15.1.**

Agenda item for the JPAC meeting in February 2005.

CJS

4.18. **SACTTI Membership – Item 15.2.**

Dr Joan O’Riordan, from the Irish Blood Transfusion Service, has now joined SACTTI.

Closed.

4.19. **Leishmaniasis – item 15.3.1.**

This recommendation went to the UK Forum on 30<sup>th</sup> July 2004 where it was approved.

Closed.

4.18. **Malaria – Item 15.3.2.**

This recommendation went to the UK Forum on 30<sup>th</sup> July 2004 where it was approved. A Concessionary letter was issued on 18<sup>th</sup> October 2004. Closed.

4.19 **Discussion Document: Deferral of plasma product recipients from blood and tissue donation – Item 15.4.**

Paper sent to the Medical Directors of the 4 Blood Services and Prof. Lindsey Davies as chair of MSBT. Closed to JPAC.

5. **UK FORUM UPDATES – JPAC 04/51 & 04/78**

Morris McClelland went through his reports JPAC 04/51 & 04/78.

5.1. **Prion Filter Working Group**

Please see item 12.1.

5.2. **JPAC Budget – additional funding**

The UK Forum approved additional funding for the web site development (BBT2 Toolkit and Operational Impact Group) on 2<sup>nd</sup> November 2004. MM, as Chair of the UK Forum, will send written confirmation to BMc as soon as possible. CJS will then inform the NBS Finance Department.

*Post meeting note: Confirmation has been received from MM and NBS Finance have been informed.*

6. **7<sup>th</sup> EDITION OF THE RED BOOK – UPDATE JPAC 04/52**
- The deadline for any outstanding chapters is now the end of January 2005. This deadline must be met if we are to publish by June/July 2005, which is felt to be the latest acceptable date.
- BMc to discuss timetable with Virge James. BMc
7. **PROPOSAL TO ESTABLISH EXECUTIVE GROUP OF JPAC – JPAC 04/53**
- JPAC approved BMc's proposal to set up an Executive Group of JPAC and its suggested membership. It was also agreed that the papers from this group would be circulated to all members of JPAC for information. BMc
8. **SAC CHAIRS AND REMITS – Progress Report**
- BMc had circulated a draft paper on the remits etc. of the SAC chairs at the end of October and asked for comments to CJS by the end of November 2004. All
9. **CHANGE NOTIFICATION – JPAC 04/54**
- BMc had produced a first attempt at a new change notification process and asked JPAC to email comments to CJS. All
10. **WEB SITE – SUB-COMMITTEE OF JPAC TO MANAGE WEB SITE – JPAC 04/55**
- JPAC approved the proposal to establish a sub-committee of JPAC to manage the web site. BMc
11. **JOINT SACTTI/SACCSD MEETING 9<sup>TH</sup> NOVEMBER 2004**
- LL gave a verbal update from the Joint SACTTI/SACCSD meeting held yesterday (9<sup>th</sup> November 2004).
- 11.1. **Policy on immunisations**
- Deferral for blood donors recently immunised with vaccines. A paper has been produced by Richard Tedder and a final version will be ready for submission to the next JPAC meeting in February 2005. LL
- 11.2. **Policy on emerging infections**
- The paper "Transfusion Transmissible Infectious Agents: basis for a policy framework" (Brian McClelland, Roger Eglin and Peter Simmond For SACTTI) will be updated and discussed at the next SACTTI meeting in January. The final version will be ready for the next JPAC meeting in February 2005. LL
- 11.3. **Analysis of deferral policy options for "MSM" & "Sub-Saharan African connection"**
- AER had requested SACTTI, with the support of ESOR (Economics Statistics & Operational Research), to initiate a study to review the deferral policy options for men

who have had sex with men "MSM" and heterosexual "Sub-Saharan Africa Connection" donors. A small task group was set up, FB has been asked to join this group, and a preliminary paper was submitted for the joint meeting yesterday. MSBT had requested an update of this paper.

It was agreed that Kate Soldan and representatives from ESOR to be invited to give a short presentation at the JPAC meeting in June 2005.

CJS

## 12. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION**

### 12.1. **Prion Reduction Filter Working Group**

- Minutes of the Prion Reduction Filter Meeting 23<sup>rd</sup> June 2004 – JPAC 04/56
- PALL Leukotrap Affinity Prion Reduction Filter Set – JPAC 04/57
- Status of PRDT Prion Reduction Filter Development – JPAC 04/58
- Terms of Reference for NBS Prion Removal Working Group – JPAC 04/59
- Prion Reduction Filters: Position Statement for MSBT – JPAC 04/60

These papers were circulated for information only and were **not for onward distribution**.

This was initially set up as an NBS working group, but it was agreed by the UK Forum that it should now be UK wide working with manufacturers for the development of prion removal technology. The group will be chaired by Dr Lorna Williamson, NBS Clinical Director – Products. The next meeting will take place on 18<sup>th</sup> November 2004.

As the group is more operational than an advisory, appropriate reporting responsibilities are still to be agreed by the UK Forum. UK Forum will let JPAC know whom this group should report to when a decision has been made.

MM

### 12.2. **Calculated Microbial Risk from Blood Transfusion – Estimates of the frequency of HIV, HCV & HBV infectious donations entering the UK blood supply 2003: Components & Parameters – JPAC 04/77**

BMc asked LL to thank the SACTTI for this work.

LL briefly went through this paper for the group. SACTTI had agreed that the information should be presented as set out in the table on page 6 of JPAC 04/77 (Estimated frequency of infectious donations per million donations and x per million donations issued: UK, 2002-2003).

LL and BMc will draft a letter to the MDs and produce a position paper.

LL &  
BMc

GG asked LL if any work had been done regarding tissue donors. BMc asked GG to put together a list of questions for LL to take to SACTTI. LL would also look at what resources are required to look at acquiring this information for tissue donors.

GG &  
LL

### 12.3. **Precautions against bacterial contamination**

LL informed JPAC that SACTTI have developed standards for donor arm cleaning, diversion and testing platelets for inclusion in the new Red Book. LL to send to CJS for next JPAC meeting in February 2005.

LL

## 13. **STANDING ADVISORY COMMITTEE ON TISSUES AND STEM CELLS**

### 13.1. **Report of MSBT vCJD Working Parties – JPAC 04/61**

As time was short GG briefly went through JPAC 04/61.

2 MSBT sub-groups had been established to examine the risk management options around the potential transmission of vCJD via transplantation of bone and other tissues. The sub-group on bone is chaired by GG and the sub-group on tissues is chaired by Dr Marc Turner. These sub-groups looked at the following:

- the feasibility and impact of cadaveric vCJD testing (Sub-Group On Tissues)
- whether further processing would reduce vCJD risk (Sub-Group On Bone)
- whether previously transfused donors should be deferred whether donors should be selected on the basis of age
- the potential for importation of tissues
- the use of substitute or alternative products
- whether bone and tissue recipients should themselves be excluded from blood and tissue donation.

The working parties are to report to MSBT for the 20<sup>th</sup> January 2005 meeting.

*Post Meeting Note:* GG has been asked to update JPAC at the next meeting in February 2005.

**GG**

### 13.2. **TEARS**

JPAC noted that there was some urgency to establish a "SHOT type" system for tissues. However in view of the impending establishment of the new National Blood and Tissue Service it was felt necessary to hold back on developing detailed proposals. This matter should remain on the JPAC agenda until a plan of action is agreed.

*Post meeting note:* BMc has asked GG and Dorothy Stainsby for an update for the next JPAC meeting in February 2005.

## 14. **STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE**

### 14.1. **"30 minute rule" – guidance from JPAC**

This matter is under review by SACBC.

*Post meeting note:* Chair of SACBC will be asked to provide an update for the next JPAC Meeting in February 2005.

**BMc**

## 15. **STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**

### 15.1. **Points for JPAC from SACCSD meeting on 1<sup>st</sup> October 2004 – JPAC 04/63**

FB went briefly through this paper.

#### **Item 4 - Acupuncture**

The SACCSD had approved in principle the addition to the list of health care professionals whose clients can donate blood after receiving acupuncture, members of the British Association of Western Medical Acupuncture (BAWMA), whose membership consists principally of registered doctors and nurses. Nurses will be registered with the UKCC. This was endorsed by JPAC. BMc requested FB to prepare a change notification would be needed.

**FB**

**Item 5 - Increasing volume of blood collected to 500 ml plus samples.**

This has been raised with SACCSO. The decision was that no change could be considered until there has been a full review of the evidence and management of donation-induced iron deficiency.

**Action:** Teleconference will be arranged between SM, BMC and FB to discuss further and formulate a proposal for next the JPAC meeting.

CJS

15.2. **Draft SACCSO minutes of meeting held on 1<sup>st</sup> October 2004 – JPAC 04/64**

Circulated for information.

15.3. **Re-appraisal of the donor age criteria for the UK – Summary, recommendations and comments from Prof. Archie Young - JPAC 04/65**

SACCSO proposed that the upper age for recruiting new donors be raised to the 70<sup>th</sup> birthday, and that there be no specific upper age bar for regular repeat donors. JPAC agreed that this is a very important proposal with substantial implications. Therefore it was agreed that:

1. FB will update this paper
2. Each member of JPAC will be asked to provide a written commentary and opinion on the proposal.
3. Once these have been received they will be collated and a proposal brought back to JPAC for a decision.

FB

All

BMC

16. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS**16.1. **Leucodepletion residual risk – JPAC 04/66**

Work in progress.

16.2. **Interruption of platelet agitation – JPAC 04/67**

JPAC approved the following proposal taken from JPAC 04/67.

**Proposal**

It continues to be recommended that platelets be stored at 22°C with continuous gentle agitation.

However if agitation is interrupted as a result of laboratory equipment breakdown or extended transportation outwith the blood bank, this is not an *a priori* reason to reject them for clinical use. For platelets stored in second generation packs\*, at ambient temperature and having a 'process mean' concentration of around 1.4x10<sup>12</sup>/L, interruption of agitation for 24 hours has no adverse effect on in vitro or in vivo properties. Interruption for longer periods (48 hours) is supported by in vitro studies but has not yet been extended to in vivo studies.

As a check, if there is any doubt, maintenance of platelet swirling is good evidence that they remain viable.

Post meeting note:

- \* Second generation packs are those suitable for more than 5 days of storage.
- \*\* The 'process mean' is the mean platelet content achieved by that particular process, (measured during process validation) rather than the specific platelet content in the actual pack (not routinely measured).
- \*\*\* This is deliberately vague because there is no precise cut-off.

This change will be included in the new Red Book and will not be covered by a separate Change Notification.

16.3. **Shelf life of red cells in additive solution – JPAC 04/68**

BMc thanked the SACBC for this paper which very fully reviews the evidence relating to red cell viability and other aspects of storage. However, before any decision can be reached on this proposal the data on bacteriological aspects of prolonged storage also needs to be reviewed.

**Action:** SM and LL to submit paper again with the bacteriological evidence.

**SM &  
LL**

16.4. **Update on upper limit of pH**

No update available yet. SM is still awaiting information from BEST (Biomedical Excellence for Safer Transfusion)

**SM**

16.5. **Requirements for assessment of component quality for prion reduction filters – JPAC 04/69**

Circulated for information.

17. **ANY OTHER BUSINESS**

- 17.1. MF informed JPAC that, as part of the reconfiguring the Department of Health's Arm's Length Bodies, the NIBSC will be merging with the Health Protection Agency (HPA).
- 17.2. AER informed JPAC that in the light of the Directive's coming into force date, 8<sup>th</sup> February 2005, the MHRA have been provisionally identified as the Competent Authority subject to further discussions as to its role and responsibilities.

18. **DATE AND VENUE OF NEXT MEETING**

The next meeting will take place on Wednesday 23<sup>rd</sup> February 2005 at the West End Donor Centre in London

**The meeting closed at 16:40**