Joint UKBTS/HPA Professional Advisory Committee

Minutes of the 48th meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 10th March 2011

Meeting Commenced at: 11:03

PRESENT

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Mr Ian Bateman	**(IB)**	-	Representing the Quality Managers of the 4 UK Blood Services
Prof Ian Franklin	**(IMF)**	-	National Medical Director, Irish Blood Transfusion Service
Mr Nigel Goulding	**(NG)**	-	Medicines & Healthcare products Regulatory Agency
Dr Patricia Hewitt	**(PEH)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Dr Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC (Chair)
Dr Christiane Niederlaender	**(CN)**	-	Human Tissue Authority (HTA)
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Chris Prowse	**(CP)**	-	Standing Advisory Committee on Blood Components
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant
Dr Phil Yates	**(PY)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Health Protection Agency (HPA)

INVITED GUESTS

Ruth Parry	-	For item 7 only
Prof Richard Tedder	-	For item 7 only
Dr Stephen Thomas	-	Observer

SM welcomed Ian Bateman to his first JPAC meeting. Ian has taken over from Bruce Cuthbertson as the Quality Representative on JPAC.

SM also welcomed IF in his new role as National Medical Director of the Irish Blood Transfusion Service and PY to his first meeting as the Chair of the new SAC on Tissues and Cellular Therapy Products, although PY had attended previous meetings as acting chair of the SAC on Tissues.

As CP is retiring on 1st May this would be his last JPAC meeting. SM thanked CP for all his hard work as a member and latterly Chair of the SAC on Blood Components. The closing date for expressions of interest in the post of Chair of SACBC is 25 March 2011.

SM also informed JPAC that Dr Steve Thomas, attending this meeting as an observer, is taking over from Nick Watkins as the SaBTO representative on JPAC.

Action

1. APOLOGIES

Dr Joanne Murdock	**(JM)**	- Acting Medical Director, Northern Ireland Blood Transfusion Service
Prof James Neuberger	**(JN)**	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Prof Marc Turner	**(MT)**	- Medical Director, Scottish National Blood Transfusion Service
Dr Nick Watkins	**(NAW)**	- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Nay Win	**(NW)**	- Standing Advisory Committee on Immunohaematology

2. MINUTES OF THE LAST MEETING HELD ON 11 NOVEMBER 2010 – JPAC 11-02

The minutes were approved as a true record of the meeting.

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 11-03

3.1 Review of high titre anti-A/B testing of donors within the National Blood Service (NBS) INF/MED/MA/004/02 – JPAC 10-40 - item 3.4

The trial at the Welsh Blood Service is now under way and NW will feed back the results when available. **NW**

The question of whether the current wording of the label as Neg:HT, to indicate negative for high titre was the best way of providing information for hospitals , will be discussed at a meeting on 18 April between SM, LL, BC and CP. **SM, CP & LL**

3.2 Consent for Transfusion – item 3.8

SM has discussed this issue with Catherine Howell (CH) and offered JPAC's help.

There is a meeting of the Consent Sub-Group in early April where they are going to work through the action plan and allocate key responsibilities & timeframes.

CH will take JPAC's offer of help to the meeting and feed back if they need any support.

3.3 Reinstatement of 'non-specific' reactive tissue donors v1 – JPAC 10-65 – item 4.1

PY informed JPAC that the paper by Kitchen *et al* had been used as the basis for the change request and should have been attached as additional information to the summary sheet JPAC 10-65 for the November meeting.

Prior to his retirement from the SAC on Tissues Roger Eglin had requested Su Brailsford, of the NHSBT/HPA Epidemiology Unit, to add residual risk values for HBV, HCV, HIV and HTLV for tissue donors to their work list. Once this information was available PY would bring it back to JPAC. **PY**

Action

Developing a Risk Assessment Framework

SM will take this forward.

Post Meeting Note: The first draft of the JPAC Safety Framework will be discussed at the next JPAC Executive Working Group on 26 May.

3.4 Dengue Virus risk assessment – JPAC 10-67 – item 5.2

Introduction of donor deferrals for infectious disease will be considered as part of the development of a risk assessment framework. Action: SM **SM**

3.5 Xenotrophic Murine leukaemia Related Virus (XMRV) risk assessment update v2 – JPAC 10- 68 – item 5.3

At the previous meeting LW had informed JPAC that Organ Donation and Transplant had followed up 20 recipients from donors with a history of CFS for 3 years and none have symptoms of CFS/ME. This work had been written up as an urgent letter to the Lancet.

LW will get the final version of the paper to CJS for circulation to JPAC. **LW**

3.6 Recommendations for Transfusion Related Acute Lung Injury (TRALI) risk reduction – JPAC 10-71 – item 6.1

This recommendation will go in the next edition of the Red Book and SB has included the advice in Chapter 3.

It was agreed that the paper would not go on the website until the next edition of the Red Book has been published.

As NW was unable to attend this meeting his action to update this paper, with the edition of recommending retesting female donors following a pregnancy, will be carried over to the next meeting.

Post Meeting Note: The summary sheet to this paper has been amended to include the following sentence "To retest female donors after pregnancy".

3.7 Quality Control standards for monitoring Fresh Frozen Plasma – JPAC 10-73 – item 8.1

SM, SB and CP met with the MHRA, following the previous JPAC meeting in November, to discuss this paper and other matters. The MHRA have taken the paper to the EU Competent Authorities meeting and have asked for feed back but are still awaiting further comments. NG will report back to JPAC in June **NG**

Potential changes to the EU Directive were also discussed. It was felt that if changes are to be made then it would more profitable to make several at once, rather than single changes, as this will require change to the law, both in the EU and in the UK.

Action: SB, CP and SM to consider which changes should be proposed. **SM, SB & CP**

3.8 JPAC Position Statement on Granulocyte Therapy – JPAC 10-78 – item 8.6

Action

At the last JPAC meeting there was a discussion about the risk of issuing non-irradiated granulocytes and it was felt that one option would be to withdraw codes for the non-irradiated products. This was investigated by CP and is not compatible with current processing technology.

4. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

4.1 Recommendations on a change to the Donor Selection Guidance for Pregnancy – JPAC 11-04

The paper makes recommendations for the revised donor selection guidelines as current long standing guidance is not in line with BSQR 2005.
JPAC endorsed the recommendations and a Change Notification will be issued.

Post Meeting Note: Change Notification No 1 2011 – Pregnancy was issued to Quality Managers on 13 April 2011. Source files for the guidelines will be available on the website on 10 May and published on the Live site on 7 June 2011.

4.2 Recommendations on a change to the Donor Selection Guidance for Trying to Conceive – JPAC 11-05

This paper brings the guidance for whole blood and component donors and tissue donors into line. PY confirmed that this also applies to cord blood.

JPAC endorsed the recommendations and a Change Notification will be issued.

Post Meeting Note: Change Notification No 2 2011 – Trying to Conceive was issued to Quality Managers on 13 April 2011. Source files for the guidelines will be available on the website on 10 May and published on the Live site on 7 June 2011.

4.3 Recommendations on a change to the Donor Selection Guidance for Immunization – JPAC 11-06

JPAC endorsed the recommendation to amend the DSG guidance on Immunisation to allow 4 week deferral for live vaccine while retaining the 8 week deferral for Smallpox vaccine and a Change Notification will be issued.

Post Meeting Note: Change Notification No 3 2011 – Immunization Live was issued to Quality Managers on 13 April 2011. Source files for the guidelines will be available on the website on 10 May and published on the Live site on 7 June 2011.

4.4 Recommendations on a change to the Donor Selection Guidance for Syphilis – JPAC 11-07

JPAC endorsed the recommendation to amend the DSG guidance on Syphilis with new wording to allow a second discretion "If the potential donor did not require treatment and it is more than 12 months since the infected partner has completed treatment, accept". A Change Notification will be issued.

Post Meeting Note: Change Notification No 4 2011 – Syphilis was issued to

Action

Quality Managers on 13 April 2011. Source files for the guidelines will be available on the website on 10 May and published on the Live site on 7 June 2011.

4.5 New Donor Selection Guidelines entry for Porphyria – JPAC 11-08

The current DSG does not contain any advice on Porphyria. This paper had been prepared in the light of a number of recent requests for guidance.

JPAC endorsed the recommendation to add information on Porphyria to the DSG and a Change Notification will be issued.

Post Meeting Note: Draft Change Notification No 5 2011 – Porphyria was issued to Quality Managers on 13 April 2011. Source files for the guidelines will be available on the website on 10 May and published on the Live site on 7 June 2011.

4.6 Metal on Metal Hip replacements – JPAC 11-09

The SACCSD has received some enquiries about the potential risk of metal on metal hip replacements with regard to possible raised levels of cobalt and chromium irons in the blood. The SACCSD sought expert advice with the conclusion that no deferral of patients with these prostheses is required.

JPAC endorsed the recommendation that there should be no change in current guidance.

4.7 Recommendations on Donor Height and Weight – JPAC 11-10

This paper was discussed at length.

The paper evaluated available evidence of the risk of accepting blood donors with low estimated blood volumes (donation volume should not exceed 15% of the donors blood volume). There is an increased risk of faints if this limit is exceeded and potentially a risk of loss of donors.

JPAC approved the recommendation to apply this change of policy (to apply the principle that the donor should have an estimated blood volume of at least 3,500 mls) to donors under 20 years of age in the first instance, supported by monitoring and regular review of adverse events in all donors, and that this should be reviewed in one year with a view to extending the age group. It was agreed that this should be referred to the UKBTS Forum before any further action is taken.

Action: SM to take the UKBTS Forum meeting in June. **SM**

5. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

5.1 Dengue Virus risk assessment (5) 16-11-10 – JPAC 11-11

JPAC accepted this new version of the risk assessment which replaces the paper presented at the JPAC meeting on 11 November 2010. This updated version contains data published from studies on blood donors in Puerto Rico.

5.2 Assessing the uncertainty in the UK residual risk estimate model for

Action

blood donors – JPAC 11-12

The proposal in this paper is to present residual risk estimates as 95% interval estimates, and to present the data for the UK as a whole and on a rolling 6 year period. At the moment the proposal is only for blood donors.

The table in the paper is an example of the figures which would be obtained using the new method of calculation, although it may be preferable to present these in a more user-friendly form e.g. 1 in x million donations. There was concern that presentation of a higher and lower limit might lead to concentration on the "worst case scenario" rather than the fact that the risk is likely to lie somewhere between the two. PEH felt that this should not be a problem given the very low risks involved.

PEH was asked to check when the next estimates will be available, and whether the risk estimates for earlier periods could be "converted" to the same format to allow for comparison over the years. **PEH**

6. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

6.1 Change control for initial discard limits – JPAC 11-13

JPAC 11-13 is a change control version of the full paper which came to, and was approved, at the last JPAC meeting in November. JPAC endorsed the change and a Change Notification will be issued.

Post Meeting Note: After further discussion between SM and RC, on 24 May, it was decided that a Change Notification will not be issued at this time. RC will take this back to the next SACBC meeting and a decision will be made on how this information should be presented in the next edition of the Red Book.

6.2 Revised Chapter 7 of the Red Book – JPAC 11-14

CP went through the revised chapter for the Group. The following comments were made.

- Page 5, Section 7.3, The starting material, 6th paragraph, SACTTI are not using the term "falsely reactive", they are using the term **"non specific reactive".**
- Page 5, Section 7.3, The starting material, last sentence should read ".....UK have been leucodepleted since **1999"**.
- Page 8, Section 7.4, Component labelling, 2nd paragraph. Take out reference to the **Component Portfolio**.
- Review the use of the words "**Blood Centre**" throughout the chapter.
- Page 12, Section 7.10 – wording should be ".... or an electronic equivalent".

Post Meeting Note: Completed Chapter 7 has now been received at the JPAC Office.

CP is seeking permission from Blackwells to reproduce "Figure 1" on page 3. **CP**

6.3 Prion reduced red cell concentrates – quality monitoring – JPAC 11-15

This paper, which discussed validation of a proposed assay (modification of a Factor IX ELISA) for the quality monitoring of prion reduced red cell

Action

concentrates, was endorsed by JPAC. It will also be discussed at the next Prion Working Group meeting. If approved there the requirement for the assay, as part of quality monitoring, can be included in the specification for the prion reduced red component, which will be posted in a new trial component section of the JPAC website.

Action: ST to take to the Prion Working Group and SACBC chair to finalise the component specification. **ST & RC**

6.4 Prion reduced red cell concentrates for exchange transfusion – JPAC 11-24

This paper was an executive summary of the work done on developing this new component. This will also be reviewed at the Prion Working Group and if approved the specification will be posted in the new trial component section of the JPAC website. **Action:** ST to take to the Prion Working Group and SACBC chair to finalise the component specification. **ST & RC**

6.5 Use and naming of Platelet Additive Solution (PAS) – JPAC 11-25

JPAC endorsed the recommendation that entries in the Red Book should remain as "PAS", but move towards adoption of the ICCBBA (International Council for Commonality in Blood Banking Automation) PAS terminology over the next 18 months.

1:30 Maria Zambon arrived

7. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

7.1 Blood Components – Proposed model for SNOMED-CT – JPAC 11-26

LL went through this paper for the Group. The paper is not in its final form and is open for comment. Once finalised it will be taken to SNOMED UK to become part of SNOMED-CT technology and then international SNOMED and international ISBT.

LL asked JPAC members to pass the paper on to any "experts" for comment. SM will discuss with Mike Murphy to pass on information to the National Blood Transfusion Committee.

Post Meeting Note: A copy of the paper was sent to Mike Murphy (31-03-11) for the IT subgroup of the National Blood Transfusion Committee and any other interested parties. John Muircroft (SNBTS) and Paul Ashford (ICCBBA) have both passed their comments on to Emma Melhuish, Senior Pharmaceutical Informatics Specialist at NHS Connecting for Health.

LL will keep JPAC updated on progress. **LL**

8. JPAC WEBSITE TRANSFUSIONGUIDELINES.ORG.UK

8.1 Website Manager Post – update

SM informed JPAC that Geoff Poole, Managing Director of WBS, had been helping to facilitate this post through the WBS recruitment process on behalf of JPAC. The job description and person specification had been updated and the post had been graded as an AfC band 7. It is hoped that the vacancy will

Action

appear on the NHS Jobs website within the near future.

8.2 Proposal to include dedicated Patient Information pages on the JPAC website – JPAC 11-16

DN was asked to review the proposal in the light of the committee's comments. Although most, but not all, members were supportive of putting patient and public information on the JPAC website members felt that, as this is a UK website, it should be open to all the UK countries. However, strong reservations were expressed about the management of the web pages, version control and the potential work involved answering enquiries from the general public.

Post Meeting Note: It has now been decided that the dedicated patient information pages will be hosted on the Blood.co.uk website.

9. HPA/JPAC LIAISON AND BUSINESS PLANNING

Presentation by Prof Maria Zambon and Prof Richard Tedder and Ruth Perry. A copy of the presentation will be circulated to JPAC.

The presentation described a proof of concept intervention study (SiMPLE) in which patients with proven H1N1v who were likely to require mechanical ventilation would be treated early with "convalescent" plasma from donors with high titre antibody to H1N1.

Some things did not go well, in that the donor response to the request to be a donor was lower than expected and some of the donations were collected late after the infection by which time the antibody levels had waned. A number of things went well including the close working together of HPA, NPSF and NHSBT and the offering of plasma packs for treatment of severely ill patients on compassionate grounds in early 2011.

The conclusions were:

- We were able to achieve our goals by playing to the strengths of each of the groups involved
- Cooperation between organisations is essential – this can be achieved by communication at all levels
- Speed is of the essence
- Early treatment of patients is essential
- We probably need to start planning now, for next pandemic

Post Meeting Note: A copy of the presentation was circulated to JPAC, with the draft JPAC minutes, on 31 March 2011.

10. RED BOOK – 8TH EDITION

Some of the chapters have been submitted. CJS and SM are setting up a meeting with the publishers and will keep JPAC updated on progress.

11. SaBTO

Action

11.1 Summary of the thirteenth meeting on 18 January 2011 – JPAC 11-17

LW went through summary report for the Group.

1. Patient consent for transfusion – moving forward
2. Organ donation by those with cerebral tumours.
3. Review of blood donor selection - There was a request for additional analysis but it is hoped that the recommendation will be finalised at the SaBTO meeting on 3 May.
4. Cytomegalovirus (CMV) transmission by blood transfusion – SM is representing the 4 UK Blood Services on the SaBTO CMV sub-group. This will also be discussed at the SaBTO meeting on 3 May.

3:00 pm LW left the meeting.

12. ANY OTHER BUSINESS

12.1 Event driven Audit of JPAC – JPAC 11-23

SB went though the report for JPAC. The contents were noted and the report will go to the next UKBTS Forum meeting in June.

Post Meeting Note: This paper was submitted to the UK BTS Forum meeting on 17 June.

12.2 Proposed JPAC meeting dates 2012

- 8 March
- 28 June
- 8 November

These dates were approved.

12.3 Consultation on Public Health

SI drew the group's attention to the Consultation on Public Health which is available on the DH website.

The meeting concluded at: 15.17

13. DATE & VENUE FOR FUTURE JPAC MEETINGS

2011

- Thursday 30 June - Association of Anaesthetists, London
- Thursday 10 November - Association of Anaesthetists, London