APPROVED 11/03/2010

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 44th meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 12th November 2009

Meeting Commenced at: 11:00

PRESENT

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
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 Edwin Massey	**(EM)**	-	Standing Advisory Committee on Immunohaematology
Dr Joanne Murdock	**(JM)**	-	Acting 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 (Joined the meeting at 13:30)
Prof. David Pegg	**(DP)**	-	Standing Advisory Committee on Tissues
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Stephen Thomas	**(ST)**	-	Standing Advisory Committee on Blood Components
Dr Nick Watkins	**(NAW)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO (Observer)
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant

ACTION

1. APOLOGIES

Dr Bruce Cuthbertson	**(BC)**	-	Representing the Quality Managers of the 4 UK Blood Services
Prof. Ian Franklin	**(IMF)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr Rachel Green	**(RG)**	-	Standing Advisory Committee on Stem Cells
Dr Kieran Morris	**(KM)**	-	Acting Chief Executive, Northern Ireland Blood Transfusion Service
Dr Chris Prowse	**(CP)**	-	Standing Advisory Committee on Blood Components
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
Prof James Neuberger	**(JN)**	-	UK Transplant

SM welcomed Nick Watkins and Joanne Murdock to their first JPAC meeting and also Steve Thomas (deputising for Chris Prowse) and Edwin Massey (deputising for Nay Win).

2. MINUTES OF THE LAST MEETING HELD ON 7TH JULY 2009

ACTION

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

1. Item 4.1.4. The title should say ".....within 4 months of event."

2. Item 6.3. It was noted that the summary sheet for JPAC 09-40 was incorrect and point 2 in section 6 should read "To note the attached report on apheresis red cells indicating that 6 or 8 hours at ambient temperature has no appreciable effect on red cell quality (C-079) up 35 days storage."

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 09-66

3.1 JPAC Position Statement – Granulocyte Therapy - item 3.1

LW informed JPAC that the results from the study being run by NHSBT and the Anthony Nolan Trust will not be available until 2011. At the previous JPAC meeting it was agreed that before changing policy the results of the study should be completed and taken into account. Therefore JPAC's Position Statement should remain unchanged.

3.2 Leishmaniasis risk assessment v1 (JPAC 09-08) – item 3.3

PEH has referred this paper back to Peter Chiodini for information regarding the pathogenicity/incubation period. **Action**: PEH to bring to the next JPAC meeting in March 2010. **PEH**

3.3 Estimates of the frequency (or risk) of HBV, HCV, HIV and HTLV (type I) potentially infectious donations entering the UK blood supply, 2002 – 2007 (JPAC 09-12) – item 3.5

PEH will send the revised paper to CJS to circulate to JPAC to approve and, when approved, post on the JPAC website. **PEH**

3.4 DEHP blood bag symbol v1 (JPAC 09-14) – item 3.7

This symbol will appear on the base label and will be covered up by any oversticks. It was agreed that information on this should be included in the UK and the individual Blood Services portfolio. SACIT to update relevant section of the Red Book in the next edition. Taken off Actions list.

3.5 Reduce minimum donation interval to 8 weeks – item 4.1.6

SB informed JPAC that this had been referred back to the SACCSD and not approved.

3.6 New data on temperature deviations and request for input on bacterial validation – JPAC 09-39 – item 6.3

ST informed JPAC that they will be going through the protocols at a meeting on 30th November with the Chair of the SACTTI bacterial sub-group. **Action:** CP / PEH will report back to JPAC when the work is completed. **CP / PEH**

3.7 High titre anti-A/B testing of donors within the National Blood Service (NBS) INF/MED/MA/004/02 – JPAC 09-42 – item 7.1

ACTION

EM informed JPAC that Nay Win has now contacted each of the Blood Services with regard to looking at the cost and feasibility of introducing IgG testing. SM asked for a written report for the next JPAC meeting in March 2010. **NW**

3.8 Prion Assay Working Group – item 14.1

This working is ongoing and until further information is available this will be taken off the "Actions List".

4. PANDEMIC INFLUENZA

4.1 Swine flu Immune Plasma Evaluation (Simple) Study – involvement and implications for UK Transfusion Services – JPAC 09-67

The study proposals were noted with interest.

NG confirmed that this should not be considered as a new product and therefore does not need to be referred to the MHRA as such. JPAC agreed that this should be allowed as a trial component and approved the use of targeted and possibly first time donors to provide immune plasma for the purposes of the study.

4.2 Use of non-accredited (first time) donors for component preparation – discussion of potential changes to current practice and guidelines to increase blood supply during pandemic flu – paper circulated to JPAC on 16 July and comments received – JPAC 09-68

It was noted that the figures quoted in this paper for residual virus risk are not up to date and that the actual risk is probably less, considering that genome testing is being implemented.

It was agreed that there was no urgency to take forward these changes at present.

4.3 Pandemic flu preparedness & proposed amendments to the Blood Directive

Directive 2009/135/EC came into force on 3rd November 2009 and now needs to be transposed into UK law. NG informed JPAC that he had had a preliminary meeting with the lawyers on 11th November.

There was discussion of the trigger factors for implementation of the derogations. These had been discussed in the paper "Potential Trigger points for changes to the BSQR 2005 donor selection criteria in the event of an Influenza epidemic causing risk to the blood supply" – sent to the MHRA, and copied to JPAC, on 27 August. JPAC felt the suggested triggers of flu reaching epidemic levels as the 'on switch', and adequate stock levels being the 'off switch' were sensible. With regard to the latter, the paper suggested that the trigger should be stock levels of 5 days of all groups, although this was thought to be quite generous.

Raised at JPAC Executive Working Group meeting - ? issue relevant Change Notifications. Action: SM **SM**

ACTION

5. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

5.1 Proposed specification for red cells, prion filtered (leucodepleted, in additive solution) – JPAC 09-69

JPAC approved the following specifications:

- 8.32 Red Cells in Additive Solution, Leucocyte Depleted, Prion Reduced
- 8.33 Red Cells in Additive Solution, Leucocyte Depleted, Prion Reduced, for neonates and infants
- 8.34 Red Cells for Intrauterine transfusion, Leucocyte Depleted, Prion Reduced

Specification 8.35, Red Cells for Exchange Transfusion, Leucocyte Depleted, Prion Reduced, still needs some questions answered and was referred back to SACBC.

As this is a new product, the European Commission will need to be notified. **SM**

Action: SM will write to NG informing him of the finalised specification.

5.2 Update to guidance on prion filter red cell evaluation – JPAC 09-70

This is an updated version of the paper "Validation of Blood Component Quality Following Prion Removal – July 2007" which is on the website.

ST informed JPAC of an amendment to Table 2. In vitro assessment of FFP on page 6 – all four "desirables" should be changed to "Y".

With this change JPAC endorsed this updated guidance.

Post Meeting Note: This paper "Validation of Blood Component Quality Following Prion Removal Procedures for Red Cell Components" has been updated and posted in the Document Library on the JPAC website (January 2010).

5.3 HbS testing of neonatal red cell components – JPAC 09-71

JPAC endorsed addition of the following phrase:

"Unless the Blood Centre recommends screening is unnecessary, the component should be Haemoglobin S screen negative."

(which is already stated in sections 8.19, 8.20 and 8.21) to section 8.22 Red Cells for Neonates and Infants, Leucocyte Depleted and section 8.23 Red Cells in Additive Solution for Neonates and Infants, Leucocyte Depleted of the Red Book. Action: CJS to draft the appropriate Change Notification and send to CP and ST.

Posting Meeting Note: Change Notification No 1 2010 – HBs testing for neonatal red cell components issued 14 January 2010.

5.4 Trial product specifications and product codes – JPAC 09-72

In principle JPAC endorsed the setting up of a special category of product specifications and associated product codes to address trial products, which

ACTION

may include a separate section on the JPAC website. However, it was agreed that more thought needed to be given to its implementation and management.

Action: SACBC and SACIT to take forward. **CP & LL**

5.5 To remove upper pH limit from Red Book specification for platelets (all types) – JPAC 09-73

After further discussion and advice from NG (MHRA) it was decided that, as we are compliant with the Directive, there is no need to amend these specifications at this time.

5.6 CE marking of Medical Devices, notes of meeting with the MHRA 9th July 2009 – JPAC 09-74

After the last JPAC meeting, LW, SM, CP met with Richard Gutowski and Louise Mulroy of the MHRA (Medical Devices) to discuss the CE marking process for e.g. prion filters and pathogen inactivation systems - under the Medical Devices regulations there is no route for any absolute standard of efficacy to be set.

Changes to legislation for medical devices will require a more robust level of clinical evidence from March 2010. These are orientated at safety rather than efficacy.

After discussion JPAC agreed that there is nothing more that can be done other than to write our own specifications to define efficacy when it comes to EU tender.

5.7 Report on the Granulocytes in Neutropenia (GIN) Study June 2009 for Consideration of Optimised Granulocyte Component inclusion in the Guidelines for the Blood Transfusion Services of the UK (Red Book) – JPAC 09-89

SM thanked EM for this paper. This had been discussed before, but JPAC had requested more safety information.

JPAC approved the addition of Granulocytes, Pooled, in Additive Solution and Plasma, a blood component produced by pooling and secondary processing of the granulocyte rich buffy coat layers of ten whole blood donations, to the Red Book.

Action: ST to make minor revisions to component specification to include a volume specification – EM to send ST details of volume. **EM/ST**

As this is a new component SM will write to NG at MHRA. CJS will draft change notification and send to CP. **SM & CJS**

It was noted that the expiry time for this component differed from that of apheresis granulocytes in the Red Book (apheresis are 24 hours from collection and the new component is midnight on day 1). SACBC were asked to review available data on granulocyte function and propose a change to the apheresis expiry in line with this new component if the data support that. **CP**

6. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

ACTION

6.1 Position Statement – Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply and background paper – JPAC 09-75

This Position Statement and background paper have been on the website since May 2007 and both are due for review.

JPAC confirmed that this statement and background paper should remain on the website and that SACCSD would take responsibility for both these papers and any updates.

SACCSD would update the paper with current data. **SB**

It was noted that SaBTO were due to discuss donor deferral at their next meeting in January and therefore SB would consult with SaBTO after this meeting. **SB**

6.2 Acupuncture – JPAC 09-76

SB reviewed the current guidelines for acceptance of donors who have had acupuncture, and outlined the problems which have arisen.

The EU Directive and BSQR state that, in order to accept patients who have received acupuncture as donors without a deferral period being applied, acupuncture should be performed by a qualified practitioner. The current guidelines allow acceptance of donors who present certificates from some Associations as proof of qualification, but we have received challenges from other Associations from whom we have not accepted certificates, and practitioners who are not members of these Associations, including registered healthcare professionals. In addition, acceptance of certificates has posed a significant operational problem at sessions with confusion as to what is allowed and what is not. It was noted that there is a current move in the UK to ensure that all qualified health care professionals are on a statutory register. A legal opinion has been sought to clarify the position in law.

Following considerable discussion, the revised specification was accepted. The rationale for change as outlined in the revised specification is as follows:

Reason for Change
JPAC considers statutory registration of practitioners to afford the best overall guarantee that blood donated by acupuncture patients is safe. In the absence of statutory regulation of acupuncture, there is currently no single body to which all acupuncturists are accredited, and so to continue with the approval of one or more organisations would necessarily mean that others of possibly equal merit were excluded from approval. Voluntary registration with a non-statutory body cannot provide assurance as to how high the standards of an organisation's members are or how diligent the non-statutory regulator is in enforcing them or the practitioner in applying them. Practitioners who choose not to join a voluntary register are still able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body. There is no way of policing the enforcement by voluntary associations of the standards they require of their members as the organisations are not subject to supervision by the Council for Regulatory Healthcare Excellence (CHRE). Nor is there currently any external, independent consideration of "fitness to practise" cases referred to voluntary regulators. While statutory regulation cannot guarantee the absence of risk, its primary aim is to deliver enhanced patient safety and public protection.

ACTION

Statutory "protection of title" means that donor centres can safely assume that a person who practises in the name of the registered profession is actually registered.

SM wrote to the British Acupuncture Council and Association of Chinese Medicine, on 25 November 2009, to communicate the change to the guidelines and the following Change Notifications to be issued on 22 December 2009.

No 32 - Acupuncture – Whole Blood Donors
No 33 – Acupuncture – Living & Deceased Tissue Donors
No 34 – Complementary Therapy – Whole Blood Donors
No 35 – Complementary Therapy – Living & Deceased Tissue Donors

6.3 Revised Whole Blood Donor Selection Guidelines (DSGs)

SACCSD have been working on a new version (v203) of the Whole Blood DSGs since last year. As well as updating the guidance the new version will incorporate a better indexing system to make it easily searchable and much more user friendly.

7. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

7.1 Guidance on molecular typing on ABO and other red cell antigens – JPAC 09-77

SM

SM will discuss further with NW on his return from leave.

8. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

8.1 ISBT 128 Project Manager – update

LL informed JPAC that we now have an Agenda for Change job description for this post and it has been graded as 8a.

LL will send the draft Person Specification and advert to SM to send to the Chief Executives of the 4 UK Blood Services. LL will lead on the appointments process. **LL & SM**

It was noted that no location for this post would be specified and therefore it can be based anywhere within the UK.

8.2 UK Product Portfolio – JPAC 09-78

A Component Label meeting had been held on 28th October.

LL informed JPAC that the portfolio has now moved to a secure hosting environment. Members of SACBC and SACIT will be given access for trialling. LL agreed to organise user accounts. **LL**

SM commented that it was important to get the four Quality Managers involved. SM will discuss further steps with CP and LL. **SM**

As well as an update on progress on the component portfolio, the meeting of 28th October discussed how to achieve commonality of the 4th quadrant of the product label. A paper on options will be tabled at the next JPAC meeting. **CP/LL**

ACTION

9. STANDING ADVISORY COMMITTEE ON TISSUES

9.1 Draft Change Notifications that affect tissue donation: Acupuncture; Body Piercing, Complementary Therapy, Endoscopy, Inoculation Injury – JPAC 09-79

JPAC approved these changes in principle, but noted that some of wording needs revising. SB agreed to revise the wording.

Action: SB to revise the wording for Acupuncture and Complementary Therapy and send to CJS for circulation to the Medical Directors for approval. **SB**

Post Meeting Note: The following Change Notifications were issued on 22 December 2009:

1. *Change Notification No 32 2009 – Acupuncture – Whole Blood*
2. *Change Notification No 33 2009 – Acupuncture – Tissues Live and Deceased, Stem Cells and Bone Marrow*
3. *Change Notification No 34 2009 – Complementary Therapy – Whole Blood*
4. *Change Notification No 35 2009 – Complementary Therapy – Tissues Live and Deceased, Stem Cells and Bone Marrow*
5. *Change Notification No 2 2010 – Body Piercing – Tissues Living and Deceased donors, Cord Blood, Bone Marrow and PBSC donors*
6. *Change Notification No 3 2010 – Endoscopy – Tissues Living donors and Cord Blood donors*
7. *Change Notification No 4 2010 – Inoculation Injury – Tissues Living and Deceased donors, Cord Blood, Bone Marrow and PBSC donors*
8. *Change Notification No 5 2010 – Endoscopy - Bone Marrow and PBSC donors*

10. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

10.1 Xenotrophic Murine leukaemia Related Virus (XMRV): Risk Assessment version 1 – JPAC 09-80

This new risk assessment was noted.

JPAC did not endorse the proposal that history of recovered ME should be actively sought from donors and a deferral applied, as there was not enough evidence to justify a change at the present time. A watching brief should be kept, while awaiting further evidence. It was noted that a prevalence study of XMRV in blood donors will be carried out, but that there has been no evidence to date of transfusion-transmission of XMRV, nor corroboration of the association of XMRV with chronic fatigue syndrome. There have been previous occasions (cf HHV8, hepatitis G) where a risk to transfusion recipients has been postulated and never subsequently proven, or where such a risk has been positively refuted.

11. EUROPE

11.1 Report of the European Commission meeting of the Competent Authorities for blood and blood components (Article 25 Directive 2002/98/EC) on 27 & 28 January 2009 at the EU Committee of the

ACTION

Regions, Brussels – JPAC 09-81

NG went through his paper which had been tabled at the MHRA Blood Consultative Committee meeting in July.

Items to note were:

5.3.2.2. Early Warning and Response System (EWRS)

8.3. EuBIS Project (pan-European standard and criteria for the inspection of blood establishments)

9. Haemoglobin levels in donors

12. JPAC REVIEW UPDATE – JPAC 09-82

An interim report had been received from RSM Bentley Jennison and was tabled for information.

The Review Workshop had been arranged and would take place on Thursday 10th December at the Royal Society of Medicine in London.

The final report will be available before the end of December 2009.

13. SaBTO – JPAC 09-83

The following papers had been tabled for information and were all available on the SaBTO website.

- SaBTO – Summary of 7th meeting held on 14/15 July 2009
- SaBTO advice concerning organ donation and H1N1 (Swine) flu
- SaBTO further information on deferral and exclusion of blood donors July 2009

The 8th SaBTO meeting, which included the 2nd public meeting focusing on donor selection, took place on 27th October and the summary is due out this week.

NHSBT have produced a summary report from this meeting and SM will send to CJS for circulation to JPAC.

Post Meeting Note: Report by Rachel Hollingworth, Stakeholder Relations Manager, circulated to JPAC on 18th November 2009.

The 9th SaBTO meeting is due to take place on 26th January 2010 and the following are possible agenda items:

- Pathogen inactivation
- Donor deferral
- Informed consent

14. UK BTS FORUM – JPAC 09-84

SM went through JPAC 09-84 – feedback from the last UKBTS Forum meeting on 18th September 2009.

ACTION

15. ANY OTHER BUSINESS

15.1 No items were discussed under AoB.

The meeting concluded at 15:20

16. DATE & VENUE FOR FUTURE JPAC MEETINGS

2010

- Thursday 11th March - Association of Anaesthetists, London
- Thursday 8th July - Association of Anaesthetists, London
- Thursday 11th November - Association of Anaesthetists, London