Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 45th meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 11 March 2010

Meeting Commenced at: 11:00

PRESENT

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
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
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 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 14:00)
Dr Chris Prowse	**(CP)**	-	Standing Advisory Committee on Blood Components
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology

ACTION

1. APOLOGIES

Dr Rachel Green	**(RG)**	-	Standing Advisory Committee on Stem Cells
Prof James Neuberger	**(JN)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Prof David Pegg	**(DP)**	-	Standing Advisory Committee on Tissues
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

2. MINUTES OF THE LAST MEETING HELD ON 12 NOVEMBER 2009

The minutes were approved as a true record of the meeting with the addition of more clarification about the reasons for JPAC approving the decision on acupuncture. The following text has now been added to item 6.2.:

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

ACTION

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."

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 10-03

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

It was agreed that this would be taken off the "Actions List". CP will take back to SACBC and then bring to JPAC.

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

NW is awaiting further information and will bring back to the next JPAC meeting on 8 July. **NW**

3.3 Pandemic flu preparedness & proposed amendments to the Blood Directive – item 4.3

Commission Directive 2009/135/EC was issued on 3 November 2009 allowing temporary derogation to certain eligibility criteria for whole blood and blood components donors. SB and SM have prepared the relevant Change Notifications.

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

Discussed under item 7.1.

3.5 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 09-38 – item 5.7

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 it is supported by the data.

Post Meeting Note: It was agreed at the JPAC EWG on 20 May at this would be included in the revision of the next Red Book.

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

ACTION

Su Brailsford is collecting UK data and will bring back to next SACCSD meeting.

IF commented that SaBTO has established a working group to look at this issue. SB to discuss with Nick Watkins **SB**

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

Stan Urbaniak has agreed to continue to lead the SACIH DNA Working Party and prepare new guidance for the next edition of the Red Book.

4. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

4.1. Estimates of the frequency (or risk) of HBV, HCV, HIV and HTLV (type I) potentially infectious donations entering the UK blood supply, 2003-2008 - JPAC 10-04

PEH went through this update for the Group. The parameters used have changed slightly.

A query was raised with respect to footnote 2 (window period 4 days for HCV).

PEH will check the information in footnote 2. Once this has been confirmed the update can be posted on the JPAC website. **PEH & CJS**

4.2 Estimates of the frequency (or risk) of HBV and HCV potentially infectious surgical bone donors being missed by testing, England 2003 – 2008 – JPAC 10-05

Several members of JPAC found the way the figures were presented in the table confusing.

PEH agreed to take this back to Lisa Brant for clarification and then bring back to the next JPAC meeting in July. **PEH**

4.3 Leishmania risk assessment v2 – JPAC 10-06

At a previous meeting JPAC had requested that information on pathogenesis be included in the Leishmania risk assessment.

This risk assessment has now been updated with the relevant information and was approved by JPAC.

4.4 Toxoplasmosis risk assessment v2 – JPAC 10-07

At a previous meeting JPAC had requested that information on pathogenesis and risk for heart values to be included in the Toxoplasmosis risk assessment.

This risk assessment has now been updated with the relevant information and was approved by JPAC.

4.5 vCJD risk assessment v4 – JPAC 10-08

ACTION

This risk assessment has been updated to include: information about the probable clinical case in a codon 129 met/val heterozygote, information about the post-mortem finding in a haemophiliac, updates about prion filters and development of blood assays for vCJD.

The risk assessment was approved by JPAC. It was noted that the review date on the last page was incorrect and should say May 2010. **PEH**

4.6 Creutzfeldt-Jakob Disease Position Statement – JPAC 10-09

JPAC approved this updated Position Statement and the addition of a further question "How many patients are exposed to blood components each year and have not developed vCJD?" and its answer. Action: CJS to post on the JPAC website.

Post meeting note: Position Statement posted on the JPAC website on 7 April 2010.

4.7 Xenotrophic Murine leukaemia Related Virus (XMRV): Risk Assessment v1: supplementary information – JPAC 10-10

JPAC had agreed, at its meeting in November 2009, to keep a watching brief on developments.

SACTTI felt it inappropriate at this time to do a version 2 of risk assessment but noted more work is being done.

It was noted that a presentation on XMRV is being made by a member of the Lombardi group in the Transfusion session at the British Society for Haematology meeting in Edinburgh in April. Some SACTTI members will attend this meeting.

Some members of JPAC felt that it is very important to engage patient advocacy groups in discussions about findings such as the reported association of XMRV and chronic fatigue syndrome. The MMR story is an illustration of what can happen when patient groups are ignored. Others felt that it is not JPAC's role to initiate discussions, and that there might be dangers in different groups trying to pursue new findings with patient groups. It was felt that the XMRV issue might need referral to SABTO, in which case the route would be through UKBTS Forum via LW.

Actions: PEH to talk to Richard Tedder about what is currently happening regarding XMRV. SACTTI will keep monitoring the situation at the present time. **PEH**

4.8 NHSBT blood donor travel survey - Sharon Ross (NHSBT Market Research and Analysis) – JPAC 10-11

The results of the survey were noted and it was agreed that these should be taken into consideration in future planning of any new donor deferral criteria based on travel. It was agreed that this should go to the next UK BTS Forum meeting for noting.

Post Meeting Note: Item added to the JPAC quarterly report for the UK BTS Forum meeting on 18 June 2010.

ACTION

4.9 Bacterial screening report – Dr Ty Pitt and SACTTI Bacteria Subgroup – JPAC 10-12

The report was noted, and several questions raised.

There was a discussion about recommendation 7 (submitting all time-expired concentrates for testing to a reference laboratory). It was felt that the paper from Ireland had provided data about the real incidence of contamination, and that further work was not needed, although it was reported that SaBTO felt that current figures underestimated the true incidence of contamination. It was noted that there is a difference between contamination detected by screening of time-expired components, and clinical incidence of contamination. It is the latter figure which is important, since bacteria detected by screening will not necessarily lead to clinical disease.

JPAC members commented that the recommendation of the ideal method seems to relate to 7 day product, and does not make any recommendation for 5 day platelets. PEH to ask about single test system for a 5 day product. **PEH**

It was suggested that the paper should include reference to the prospective Irish and US studies. It might be helpful for CP to discuss specific comments with Ty Pitt. A second version of the paper should be presented to JPAC. **CP**
There was some discussion about putting the next version of the paper onto the website. Table 8, in particular, was felt to be helpful, but the inclusion of manufacturers' data may mean that the paper is too sensitive to be published on the web site.

A new entry for the revised Red Book should be prepared, but this should be general principles, and should not cover specific detail. **PEH**

4.10 Skin disinfection report – Dr Ty Pitt and SACTTI Bacteria Subgroup – JPAC 10-13

It was noted that this paper predominantly looks at the situation in NHSBT and that short life working groups should cross the National boundaries.

After a long discussion it was agreed that this paper should go back to the SACTTI Bacteria Subgroup asking for more information on the evidence base, a literature review and more definitive recommendations. The Subgroup would be asked to consult with the SAC on Care and Selection of Donors and the other UK Blood Services. **PEH**

4.11 Response to ECDC Threat Assessment Update February 2010: outbreak of Q fever in the Netherlands (2007-2010) – JPAC 10-14

JPAC endorsed the recommendation to take no action in the current situation to detect donors who have recently travelled to the affected areas of the Netherlands. Agreed that the issue will be kept under review, and will be reviewed when the updated risk assessment from ECDC is available, and/or if information or advice is issued by HAIRS (Human Animal Infections and Risk Assessment Group)

5. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

ACTION

5.1 Definition of oral and anal sex – JPAC 10-15

JPAC approved the definition for oral and anal sex and that this should be added (via a link) to the JPAC Position Statement "Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply" which is already on the website.

Action: Add the text and link to the Position Statement and post on the JPAC Website – CJS.

Post Meeting Note: Text and link added to the JPAC website 25 March 2010.

5.2 New version of Whole Blood Donor Selection Guidelines (DSG WB 203) – JPAC 10-16

On behalf of JPAC SM thanked SB and members of the SACCSD, especially Susan Lumley, Joanne Murdock, Jane Listen and Dave Hutton for all their hard work on the new version of the Whole Blood DSG.

It was noted that the guidance itself is not changing but the number of topics has been reduce from more than 750 to 200. These have been revised to improve clarity.

The following actions were agreed:

The PDF version will be available for the Quality Managers in April (6 weeks before 1st June) to allow the UK Blood Services to print the guidelines and train staff.

Post Meeting Note: PDF version of WB DSG 03 sent to QMs 06-04-10. Revised version (Malaria) sent 19-04-10.

The new DSG will be posted on the JPAC website on 1st June – browser and PDF version.

Post Meeting Note: WB DSG 03 posted on the JPAC website on 1st June – available in PDF and offline browser versions.

BC will inform the Quality Managers of the other UK Blood Services, asking for an agreed UK wide implementation date of 1st September and notify the JPAC Manager. **BC**

A Change Notification will be issued. *Post Meeting Note: It was decided it was not necessary to issue a Change Notification (14-06-10).*

It was noted that further work will be needed on the other Donor Selection Guidelines (Tissues and Cord Blood etc.), but as the whole blood guidance itself has not changed, this is not imperative.

NG commented that there should be a clear implementation date from the 4 Services. Implementation within 3 months of 1st June was agreed.

Post Meeting Note: Final PDF version emailed to the Quality Managers by CJS on 6 April 2010.

ACTION

6. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

6.1 Addition to 14.5.1 in the Red Book to allow rare antisera to be used in investigations – JPAC 10-17

This recommendation was approved with the following change to the last sentence - "Using rare antisera in this way must be approved and documented by Quality Assurance." Action: A Change Notification will be issued.

Post Meeting Note: Change Notification No 6. 2010 – Patient Testing – test reagents and test systems issued on 1 June 2010.

7. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

7.1 UK Product Portfolio

Pilot to test the proposed maintenance processes for the UK Blood Product Portfolio – JPAC 10-18

SACIT want to initiate a pilot to test the proposed maintenance processes for the UK Blood Product Portfolio in preparation for implementation across the 4 UK Blood Services.

CP agreed to take this forward with the help of Angela Brazier and John Muircroft from SACIT and Mark Nightingale for Quality **CP & LL**

LL had been contacted by Rick Jones from the Royal College of Pathologists (National Library of Medicine) as they have an issue around the definition of tests and are interested in taking a learning opportunity from this pilot. JPAC felt this was a useful collaboration and LL agreed to continue to liaise with the RCPath. **LL**

It was noted that the Blood Services will need to inform hospitals.

An implementation plan across the Blood Services is needed and there also needs to be a system which says we have to notify the MHRA in the event of a new component being developed. BC will take to the next meeting of the UK Blood Service Quality Managers. **BC**

Derek Norfolk arrived at 14:00

7.1.1. Examples of Red Cell and Platelet Labels – JPAC 10-35 and JPAC 10-36

LL tabled JPAC 10-35 and 10-36, examples of Red Cell and Platelet Labels.

There was considerable discussion about the options presented.

All agreed that 'Use before' was better than 'do not use after' – the latter took up an additional line of label space.

The Quality Managers need to see and discuss the options – BC to arrange. **BC**

It was also agreed that there should be consultation with hospitals and that the

ACTION

NBTC Blood Bank Managers Group might be a useful forum. In addition nurses should be consulted, possibly through TP groups. **SM**

It was noted that the message about HLA and HPA antigens on the platelet example was unclear and needs further work. **SM/CP**

All to send comments to CP **All**

7.2 ISBT 128 Project Manager – update

Expressions of interest have been received from two people. It is hoped to hold interviews in April.

Post Meeting Note: Interviews were held on 30 April and Janet Sampson, from the Welsh Blood Service, has been appointed.

7.3 DEHP Symbol

This will appear on blood bags before April. Mark Nightingale is composing a paragraph of explanation of the symbol to be included in the Components Portfolio. CP will send to CJS, for SM to send to Medical Directors for consideration of how to manage the information in their individual services. **CP & SM**

Post Meeting Note: Text of the paragraph as follows:

This symbol indicates that the plastic pack contains a phthalate plasticiser, specifically DEHP (Bis (2-ethyl (hexyl) phthalate). This is added to yield a flexible plastic and has some benefits in improving red cell storage properties. However studies have indicated that in rodents very high doses of DEHP and related compounds can induce cancer and affect reproductive capacity in rodents. Such side effects have not been demonstrated in man. While blood bag manufacturers are seeking alternative plasticisers there are currently few alternatives to DEHP. The symbol denotes that the bag contains phthalates so users are aware of the theoretical risk. Further detail may be found in Annex XIV of REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) recently published on the European Chemicals Agency website.

LL commented that SACIT have decided to consider having a chapter for the base labels and keep the component part of the label in another chapter.

8. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

8.1 Letter to Colonel Heidi Doughty regarding LyoPlas N-w – JPAC 10-19

The contents of the letter, containing an assessment by SACBC on data provided about this product, were noted. There were further discussions about whether it should be treated as a medicinal product. NG agreed to discuss with colleagues.

SM will feed back to Colonel Doughty that she should discuss with the MHRA.

Post Meeting Note: –A letter has been received from the MHRA advising that, "following a discussion with Nigel Goulding, the MHRA has now reviewed the information provided and has sent a letter to the company advising them that we would now regard this product to be a relevant medicinal product. This decision is based on the grounds that the lyophilized plasma "is prepared by a

ACTION

method involving an industrial process". SM has forwarded this to Colonel Doughty.

Dr Dick Jones left the meeting at 14:26

8.2 Progress update on prion filtered red cell specification – JPAC 10-20

This specification has been updated but requires input from MHRA on batch testing and on final chosen process to preparing product for exchange transfusion.

There was further discussion about how to ensure that filtration had occurred. It was agreed that it would not be appropriate to take infected material into processing labs. NG will write to CP with advice from MHRA. **NG**

SM will write to NG to notify that we are making this new product after the final specification is received from CP. **SM**

8.3 Specification for: "Platelets, suspended in additive solution, leucocyte depleted" – JPAC 10-21

JPAC endorsed the specification for inclusion in the "Red Book"

Action: Issue a Change Notification.

Post Meeting Note: After further review of this change it has been decided by CP and SM not to issue a Change Notification, but to amend the section in the next edition of the Red Book.

8.4 NHSBT - Review of the trial of CUSUM monitoring for blood components – JPAC 10-22

SM has tabled the Transfusion Medicine paper (*Transfusion Medicine*, 2009, **19**, 329-339) for the 6th GTS meeting in Madrid next week. SM will feedback at the next JPAC meeting in July. **SM**

8.5 Granulocytes, pooled, buffy coat derived, in platelet additive solution and plasma – JPAC 10-23

After removal of repeated instruction about removal of plastic overwraps, CN will be issued and NG informed about new product. **CP, SM & CJS**

Post Meeting Note: The specification has been sent to NG for information. Draft CN No 7 – Granulocytes, pooled, buffy coat derived, in platelet additive solution and plasma was sent to the MDs on 1 June 2010.

8.6 Systematic Reviews Initiative (SRI)

CP informed the group that SRI are looking at the 30 minute rule.

8.7 Discard Limits

CP to bring to next JPAC EWG meeting on 20 May. **CP**

9. JPAC REVIEW – JPAC 10-24

ACTION

JPAC endorsed the proposal with the addition of "Outputs" to item 10) JPAC in 3 years' time.

SI and SM had previously discussed whether the name of JPAC should be amended to reflect the change in name of NIBSC. SI will write to SM with a proposal.

Post Meeting Note: Proposals had been received from SI and were discussed and approved at UK BTS Forum meeting on 18 June.

10. SAC TERMS OF REFERENCE - JPAC 10-25

The Remits/Terms of References for the SACs need updating.
SM asked the SAC Chairs take this paper to their committees to consider what changes are required.

Post Meeting Note: Telecons were held with all SAC Chairs during May and June and revised ToRs etc. will be discussed at the July JPAC meeting.

11. CHANGE NOTIFICATION PROCESS - JPAC 10-26

The Change Notification Flowcharts were approved.

12. SaBTO

12.1 SaBTO information - JPAC 10-27

Noted.

12.2 Patient consent for transfusion - a SaBTO consultation - JPAC 10-28

It was agreed that JPAC would not comment on this consultation.

13. UK BTS FORUM JPAC 10-29

Feedback from the last UK BTS Forum Meeting on 26 February 2010 - JPAC 10-29

SM went through her report from the last UK BTS Forum which included:

- JPAC Review
- JPAC budget
- Prion Reduction and Prion Assay Working Groups
- Complaints procedure
- New edition of the Red Book

14. ANY OTHER BUSINESS

14.1 Next Edition of the Red Book

The UK BTS Forum had raised the question of whether the next edition of the Red Book should just be produced in electronic format only. Hard copies of

ACTION

the Red Book are very popular, especially with Laboratory Staff.

The JPAC Office will conduct a survey to find out what format users prefer. **CJS**

14.2 Meeting of the Competent Authorities on blood and blood components

NG had received a draft agenda for the above meeting which is taking place on 12 and 13 April in Brussels.

One of the main items for discussion is Directive 2009/135 on blood supply in the context of the Influenza A(H1N1) Pandemic.

JPAC noted the contents of the agenda and were happy to give NG any information he may need.

14.3 Expiry Date on Labels

BC is getting enquiries about what an expiry date on a label actually means. It was agreed that this information is more appropriate for the Handbook of Transfusion Medicine. DN will consider in the next rewrite of the Handbook.

14.4 Female Plasma

CP asked DN if he'd had any enquiries about using male plasma following a recent report of increase in morbidity from male plasma. DN had not had any comments or queries.

14.5 Invitro Diagnostic Medical Devices Directive – 98/97/EC

SI informed JPAC that the above directive is being revised and will send the relevant information to CJS for JPAC to consider the implications.

NG will also inform his MHRA colleagues.

The meeting concluded at 15:40

15. DATE & VENUE FOR FUTURE JPAC MEETINGS

2010

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

2011

- Thursday 10 March
- Thursday 30 June
- Thursday 10 November