APPROVED 12/11/2009

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 43rd meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 9th July 2009

Meeting Commenced at: 10:45

PRESENT

Dr Rebecca Cardigan	**(RC)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO (Observer)
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
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC (Chair)
Dr Morris McClelland	**(MM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
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 Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology

Dr Morris McClelland is retiring at the end of July 2009 and this would be his last meeting. SM thanked MM for his contribution to JPAC since 1997.

Action

1. APOLOGIES

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selectio of Donors
Dr Rachel Green	**(RG)**	-	Standing Advisory Committee on Stem Cells
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Willie Murphy	**(WM)**	-	National Medical Director, Irish Blood Transfusion Service
Prof. David Pegg	**(DP)**	-	Standing Advisory Committee on Tissues

2. MINUTES OF THE LAST MEETING HELD ON 12TH MARCH 2009

The minutes were approved as a true record of the meeting with one alteration item 4.6.

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 09-33

Action

3.1 JPAC Position Statement – Granulocyte Therapy (JPAC 08-73) - item 3.3

IMF has now received a letter from Professor David Marks, Royal College of Pathology Ethics Committee, with regard to whether it would be ethical for blood donors to donate G-CSF stimulated granulocytes.

Professor Marks responded that they considered it ethical for blood component donors to be given GCSF in order to donate granulocytes, and that the duty of care is the same as with donors of stem cells. However, before changing policy it was recommended that the results of the current UK Registry study of donors be completed and taken into account.

This study is being run by the Anthony Nolan Trust and members were unclear as to when this would be reported. LW will discuss with Cristina Navarette and transplant colleagues to seek further information. It may also be useful to review information from organ donation about altruistic kidney donation. **LW**

3.2 Chikungunya virus risk assessment v2 –(JPAC 09-05) – item 4.2

A list of references will appear on all future risk assessments.

3.3 Leishmaniasis risk assessment v1 (JPAC 09-08) – item 4.6

PEH has referred this paper back to Peter Chiodini for information regarding the pathogenicity/incubation period. **PEH**

3.4 Toxoplasmosis risk assessment v1 (JPAC 09-09) – item 4.7

PEH has now received the relevant information to update this paper.

3.5 H5N1 pandemic influenza risk assessment v2 (JPAC 09-11) – item 4.9

SM has sent the relevant information to Richard Rackham for the UK Emergency Planning Group.

3.6 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 4.10

SACTTI have looked at the error frequency again and have revised the risk assessments on the new parameters. PEH will send the revised paper to CJS to circulate to JPAC to approve and, when approved, post on the JPAC website. **PEH**

3.7 DEHP blood bag symbol v1 (JPAC 09-14) – item 5.1

CP informed JPAC that a final version is still not available.
SM has informed Catherine Howell of the changes, but will talk to Catherine again about how this needs to be communicated to hospitals. **SM**

3.8 Minimal Performance Criteria for CE marking of selected Medical Devices: A Discussion Document (JPAC 09-15) – item 5.2

CP and LW are meeting with MHRA later today (9th July 2009) and will feed back at next meeting **CP / LW**

Action

3.9 Human Tissues Authority – licence fees – item 11.1

BC informed JPAC that the idea of charging for technical agreements has been dropped.

4. PANDEMIC INFLUENZA

4.1 Regulatory issues affecting blood transfusion organisations during emergency situations (e.g. pandemic flu) – JPAC 09-46

BC went through this paper for JPAC, which was prepared on behalf of the UK BTS Quality and Regulatory Group. It was agreed that the main route for advising MHRA was through JPAC Change Notifications backed up by risk assessments when trigger levels have been reached. The type of changes fall into 3 categories:

- Relaxation of BSQR
- Relaxation of Red Book criteria
- Changes to local policies and SOPs

The following were discussed.

4.1.1 Revert to previous UKBTS limits for Haemoglobin measurements

SM to discuss further with SB as chair of SACCSD **SM**

4.1.2 Acceptance of donors within 5 days of recovery from flu

The BSQR requirement is for a 2 week deferral period following a febrile illness. SACTTI have discussed this and consider that the risk of viraemia following full recovery from flu is very small and that the deferral period could be safely reduced to 5 days. SM to write to NG with request including risk assessment. **SM**

4.1.3 Accept all donors who return from areas with endemic WNV

SACTTI considered that it was not possible at the present time to recommend a shortening of the 'WNV season'. However the proposed travel survey should provide more information about the possible benefit of putting resource into further defining donor travel criteria. Not to be pursued at the present time.

4.1.4 Accept donors with piercings/tattoos within 4 months of event

This would require a change to BSQR requirements. SACTTI are planning a review of risks associated with body piercing, but this is unlikely to be completed before October. Not to be be pursued at the present time.

4.1.5 Suspend QC monitoring of components

NG commented that this may be more important if other guidelines were relaxed as a result of the pandemic.

4.1.6 Reduce minimum donation interval to 8 weeks

To be referred to SACCSD **SB**

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4.1.7 Use of non accredited donors for component manufacture without pre-testing

It was agreed that we should ensure that component safety was retained. SM agreed to write a paper exploring options including a risk assessment for each component. **SM**

4.1.8 Accept donors with piercings/tattoos between 4 and 6 months of event.

This is acceptable within BSQR but against current Red Book guidance. It was agreed that SACTTI would provide risk assessment data and a Change Notification should be raised. This would be a permanent change, not temporary during the flu epidemic.

Post Meeting Note: Change Notification No 19 2009 Body Piercing issued on 10th August 2009.

4.1.9 Cease recall of components donated prior to the onset of flu like illness.

See below.

4.1.10 (3) Local initiatives

NHSBT propose reducing inter-donation interval to 12 weeks for a limited period. It was noted that an 8 week interval is current practice in some countries.

4.2 Pandemic H1N1V influenza mitigating actions v1 – JPAC 09-34

JPAC endorsed the contents of this paper from SACTTI, which was discussed in conjunction with JPAC 09-46.

4.3 H1N1V pandemic flu: recall of blood components from donors who report "flu-like illness" after blood donation – JPAC 09-35

JPAC endorsed the proposal from SACTTI that, during an H1N1V pandemic, recall of components from donations made prior to the onset of a flu-like illness in the donor could be discontinued without any significant anticipated risk to recipients. As this is not a Red Book requirement then it would be down to individual Services to implement.

4.4 Collection of flu 'convalescent plasma' – issues for discussion / clarification – JPAC 09-63

This paper was tabled for information following a query from the HPA as to the possibility of providing 'convalescent plasma' for seriously ill influenza patients. LW and SI agreed to update JPAC on further discussions and developments. **LW/SI**

5. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

5.1 Human parvovirus B19 (B19V) risk assessment version 1 – JPAC 09-36

JPAC endorsed the recommendation that no specific action is required with respect to transmission of B19V infection by blood component transfusion in

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the United Kingdom.

SI left the meeting.

6. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

6.1 Change Notification: Red cells in additive solution, leucocyte depleted, for large volume transfusion of neonates and infants – JPAC 09-37

JPAC endorsed the recommendation to update the "Red Book guidance" to permit use of red cells in additive (leucodepleted) for large volume transfusion in neonates and children. This is in line with updated BCSH guidance and follows consultation between the transfusion services and paediatric users of red cells.

Action: CJS to issue a Change Notification

Post Meeting Note: Change Notification No 17 2009 "Red cells in additive solution, leucocyte depleted, for large volume transfusion of neonates and infants" was issued on 29 July 2009.

6.2 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

This was discussed at length and several members wanted clarity with regard to the recommended dose size etc.

Action: CP to produce a summary of the discussion, revamp the specification and send to SM. SM will decide whether or not the paper needs come back to JPAC. **CP**

It was noted that if this is regarded as a new granulocyte product we need to inform MHRA through NG. **SM**

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

This paper was the first of a three-part study aimed at defining allowable storage deviations in temperature of blood components. It addresses the effect of temperature deviation on red cell quality. SACBC requested advice on what input is required with regard to the bacterial risk of changes. It was agreed that the SACTTI WP on Bacteria should be asked to comment. CP to write to the Chair of the WP with a copy to PEH. **CP**

Temperature deviation guidance update and new data – JPAC 09-40

There has been further correspondance about the allowed time for completion of transfusion of red cells following their removal from controlled storage. This paper reported new data on apheresis red cells, indicating that 6 or 8 hours at ambient temperature had no effect on red cell quality, and therefore it was questioned whether the completion time for transfusion could be lengthened. DN informed JPAC that the new BCSH guideline is due out in the next couple of months (still recommending a 4 hour limit), but this could be held back to get the correct information. It was agreed however that, seperate from the red cell

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quality point of view, there could be a bacterial growth risk and therefore this was also a question for the WP on bacteria. The current 4 hour limit should be retained unless there is evidence that this can be safely lengthened.

Post Meeting Note: It was noted at the JPAC meeting on 12-11-09 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."

6.4 UKBTS General Information 02: Evaluation of novel platelet components 2009 update – JPAC 09-41

JPAC endorsed the updated version. Action: CJS to post on the JPAC website.

Post Meeting Note: Updated version posted on the JPAC website 15 July 2009.

7. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

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

JPAC has asked SACIH to review the current practice on testing for high titre ABO antibodies of donors within the NBS.

JPAC supported the recommendation to continue screening all donations for the presence of IgM high titre haemolysin. The cut-off level for haemolysins should be brought down to 1/50 dilution by automated machine, which is equivalent to 1/64 saline titre (tube method detecting IgM antibodies).

JPAC also supported the introduction of IgG testing.

Action: SM asked NW to correspond with each Service to look at the cost and feasibility of introducing IgG testing and report back to the next JPAC meeting on 12th November 2009. **NW**

7.2 Proposal to amend the content of section 12.1.4 (f) colour coding of reagents in the Red Book – JPAC 09-43

JPAC approved the proposal to amend the relevant section in the Red Book.

Action: CJS to issue a Change Notification.

Post Meeting Note: Change Notification No 23 2009 – Colour Coding of Reagents was issued on 5th October 2009.

8. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

8.1 ISBT 128 Project Manager – update – JPAC 09-44

In the absence of LL CP informed JPAC that the job description for the ISBT 128 Project Manager is going through the Agenda for Change process. LL will keep JPAC updated. **LL**

Action

8.2 UK Product Portfolio – update – JPAC 09-45

The UK Blood Components Portfolio has been set up on the SNBTS server with access to SACBC and SACIT members to review. CP circulated photos of the proposed label, about which there are continuing discussions.

It was agreed that LL will put together a group including SACBC, SACIH and SACIT members to agree the label changes. SM will Chair. **SM/LL**

LL will do a costing for a server to host the portfolio.

9. UK BTS FORUM

9.1 Report back from the UKBTS Forum meeting on 12th June 2009 – JPAC 09-47

SM went through the JPAC report which included:

- Highlights from Northern Ireland – Dr Morris McClelland is retiring at the end of July
- JPAC Review
- Business case for appointment of Dr Ty Pitt as Chair of SACTTI Working Party on Bacteria
- Request for fund of a travel survey – blood donors
- Regulatory issues affecting blood transfusion organisations during emergency situations e.g. pandemic flu
- JPAC website

RJ left the meeting at 14.45

10. JPAC REVIEW – JPAC 09-48

RSM Bentley Jennison have been selected as consultants to assist with the JPAC review.

JPAC agreed, with a few additions, the contact list of Stakeholders and Associated parties – details of those people who would be interviewed by RSM Bentley Jennison as the initial part of the process.

After the interviews a workshop will be organised during which the Stakeholders etc. will discuss the findings from the interviews and options for the future work of JPAC. A possible date for the workshop is Wednesday 2nd September 2009.

11. JPAC WEBSITE (TRANSFUSIONGUIDELINES.ORG.UK) – JPAC 09-49

SM updated JPAC on the interim arrangement made for the JPAC website following the sudden death of Dr Serge Six in March.

It was agreed that a review of the website was also needed, but that this should take place after the JPAC review.

Action

12. EUROPE

12.1 Council of Europe "Guide to the preparation, use and quality assurance of blood components" - 15th Edition – JPAC 09-50

The draft contents of the 15th Edition of the guide had just been received, 8th July 2009, and had been circulated to the relevant people on JPAC for comment by Friday 7th August.

13. SaBTO

13.1 SaBTO information – JPAC 09-51

- Summary of the sixth SaBTO meeting on 28th April 2009
- SaBTO Statement on deferral of blood donors – March 2009
- SaBTO work plan April 2008 to October 2009

RC informed JPAC of the following list of items due to be discussed at July's SaBTO meeting:

- Platelets
  - Risk-reduction strategies for bacterial contamination of platelets
  - %age of platelets collected by apheresis
- Evidence base for exclusion of high-risk blood donors
- Updated MSBTO Guidance
- Pandemic flu – update
- vCJD risk-reduction strategies for blood components
  - Update on blood tests for vCJD and prion filtration of blood
  - Plasma
  - Cryoprecipitate

The next public meeting, due to take place on 27 October, will be on donor deferral issues.

14. ANY OTHER BUSINESS

14.1 Prion Assay Working Group

PEH is trying to work through the management of test results and donors for when a prion test becomes available. SACTTI will look at critical management of reactive screening tests for the Red Book. **PEH**

14.2. Next Edition of the Red Book

SM informed JPAC that, after the JPAC Review has been completed, work will start on bringing out a new edition of the Red Book.

The meeting concluded at 15:20

15. DATE & VENUE FOR FUTURE JPAC MEETINGS

Action

- Thursday 12th November 2009 - Association of Anaesthetists, London
- **2010**
- Thursday 11th March - Association of Anaesthetists, London
- Thursday 8th July - Association of Anaesthetists, London
- Thursday 11th November - Association of Anaesthetists, London