

## Joint UKBTS/HPA Professional Advisory Committee

### Minutes of the 46<sup>th</sup> meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 8 July 2010

Meeting Commenced at: 11:00

#### PRESENT

Dr Susan Barnes	<b>(SB)</b>	-	Standing Advisory Committee on Care and Selection of Donors
Dr Bruce Cuthbertson	<b>(BC)</b>	-	Representing the Quality Managers of the 4 UK Blood Services
Mr Nigel Goulding	<b>(NG)</b>	-	Medicines & Healthcare products Regulatory Agency
Dr Patricia Hewitt	<b>(PEH)</b>	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Stephen Inglis	<b>(SI)</b>	-	Director, National Institute for Biological Standards and Control
Mrs Linda Lodge	<b>(LL)</b>	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	<b>(SM)</b>	-	Professional Director of JPAC (Chair)
Dr Edwin Massey	<b>(EM)</b>	-	Standing Advisory Committee on Immunohaematology
Dr Joanne Murdock	<b>(JM)</b>	-	Acting Medical Director, Northern Ireland Blood Transfusion Service
Dr Derek Norfolk	<b>(DN)</b>	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Chris Prowse	<b>(CP)</b>	-	Standing Advisory Committee on Blood Components
Miss Caroline Smith	<b>(CJS)</b>	-	JPAC Manager (Minute taker)
Dr Nick Watkins	<b>(NAW)</b>	-	Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO (Observer)
Dr Lorna Williamson	<b>(LW)</b>	-	Medical Director, NHS Blood and Transplant
Dr Phil Yates	<b>(PY)</b>	-	Standing Advisory Committee on Tissues

#### ACTION

1.

#### APOLOGIES

Dr Rachel Green	<b>(RG)</b>	-	Standing Advisory Committee on Stem Cells
Dr Richard Jones	<b>(RJ)</b>	-	Medical Director, Welsh Blood Service
Dr Willie Murphy	<b>(WM)</b>	-	National Medical Director, Irish Blood Transfusion Service
Prof James Neuberger	<b>(JN)</b>	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Nay Win	<b>(NW)</b>	-	Standing Advisory Committee on Immunohaematology
Prof Maria Zambon	<b>(MZ)</b>	-	Director, Centre for Infections, Health Protection Agency (HPA)
Prof Ian Franklin	<b>(IMF)</b>	-	Medical Director, Scottish National Blood Transfusion Service

2.

#### MINUTES OF THE LAST MEETING HELD ON 11 MARCH 2009

The minutes were approved as a true record of the meeting with the addition of Prof James Neuberger's correct job title "Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant".

**ACTION****3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 10-39****3.1 Position Statement – Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply and background paper – JPAC 09-75 – item 3.6**

SaBTO have recently established a steering group to review donor selection in relation to sexual behaviour. The outcome of the this review is expected in January 2011.

**3.2 vCJD risk assessment v4 – JPAC 10-08 – item 4.5**

Please see item 5.8.

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

An updated report will be submitted to the next JPAC meeting on 11 November.

PEH

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

A query had been raised from SNBTS regarding the entry for pregnancy.

SB reported that the following appeared in the BSQR:

2.2. Temporary deferral criteria for donors of allogeneic donations

2.2.4 Other temporary deferrals

Pregnancy      6 months after delivery or termination, except in exceptional circumstances and at the discretion of a physician.

**Action:** SM with discuss the issue further with NG and inform IMF of the outcome.

SM

*Post Meeting Note from the UK Quality and Regulatory Group meeting held on Friday 9 July.*

*Implementation of DSG 203. Each service is targeting implementation on 1 September. 3 services are planning to use the browser version electronically.*

**3.5 Pilot to test the proposed maintenance processes for the UK Blood Product Portfolio – JPAC 10-18 – 7.1**

LL informed JPAC that the pilot has been working well and had identified some pitfalls which are being rectified. There are also development resource issues. All paid development time has been used and additional development is having to be absorbed by SNBTS and is therefore having to take second place to operational tasks.

LL had not had chance to liaise further with Rick Jones from the Royal College of Pathologists (National Library of Medicine) regarding a collaboration around the definition of tests.

LL

**ACTION**

All the Quality Managers have now seen the portfolio and are happy with this in principle. Prior to implementation this will need formal QA sign off.

**3.6 Examples of Red Cell and Platelet Labels – JPAC 10-35 and JPAC 10-36 – item 7.1.1**

BC informed JPAC that the Quality Managers would be discussing the options tomorrow (9 July 2010).

*Post Meeting Note from the UK Quality and Regulatory Group meeting on 9 July. The Group are happy with the new standardised format for CT labels.*

SNBTS had sent examples of the labels to their practitioners which were then circulated to the wards. It was agreed that this needs to be discussed further with hospitals. SM and CP will take this forward.

**SM and CP**

**3.7 DEHP Symbol – item 7.3**

SM now has the appropriate wording and will write to the MDs for consideration on how to manage the information within their individual services.

*Post Meeting Note: SM wrote to the MDs on 22-07-10.*

**3.8 Review of the trial of CUSUM monitoring for blood components – JPAC 10-22 – item 8.4**

SM tabled the Transfusion Medicine paper (*Transfusion Medicine*, 2009, **19**, 329-339) at the 6<sup>th</sup> GTS meeting in March. The outcome was not to incorporate this in the recommendations in the guide but to reference it.

SM will confirm whether or not this referred to the 16<sup>th</sup> or 17<sup>th</sup> edition of the CoE guide.

*Post Meeting Note: This will appear in the 16<sup>th</sup> Edition.*

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

After the recommended dose has been added this Change Notification can be issued.

*Post Meeting Note: Change Notification No 7 2010 issued 28 October 2010.*

**3.10 Next Edition of the Red Book**

The survey regarding the preferred format of the Red Book is now up and running on the JPAC website.

**4. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

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

In July 2009 JPAC supported a recommendation to reduce the cut off level for haemolysins to 1 in 50 dilution and introduce IgG testing. JPAC requested SACIH then to look at the cost and feasibility of this proposal. This paper

**ACTION**

presented the findings and also updated the previous version with additional information from SHOT, further information regarding additional testing of High titre IgG from the Australian Blood Services and information about a parallel project currently being undertaken by NHSBT ensuring provision of optimal platelets.

There was considerable discussion about this paper, including whether JPAC should be looking at cost effectiveness and, if so, how this could be done. There are several options for reduction in the risk of haemolysis due to incompatible platelet transfusion, one of which is high titre anti-A/B testing. It was noted that NHSBT are developing a safety framework for decision making and this may also be helpful to JPAC.

It was noted that the Welsh Blood Service are planning to do a trial investigating antibody titres of IgM and IgG antibodies in group O donors, in order to establish the required dilution for any IgG anti-A/B test and identify the level of product likely to be affected. The results will be brought back to JPAC.

**Action:** NW

NW

SM will discuss performing an option appraisal of strategies, to reduce the risk of haemolysis from incompatible platelet transfusions, with the NHSBT/DH Analytical Steering Group. **Action:** SM

SM

It was also questioned 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. This could be discussed with users in conjunction with wider discussions about red cell and platelet labelling. **Action:** CP and SM.

CP & SM

## 5. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS**

### 5.1. **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 10-41**

Risk estimates for 2004 to 2009 have been done but, due to illness, were not presented at SACTTI 2 weeks ago.

The latest figures include data following introduction of hepatitis B NAT screening (all blood services except SNBTS), which has picked up 4 infections in long-term donors (2 acute and 2 chronic). However, risk estimates are based on 3 year cycles, and the estimated risk for 2006 – 2009 is no different from previous years.

It was agreed that PEH will consult with SACTTI offline to approve the final document, and SM will sign off for JPAC. The data will also require sign off by Mary Ramsay for the Epidemiology Steering Group.

*Post Meeting Note: These figures are included in the Epidemiology Team Annual Report which was approved by the Steering Group and published at the end of August 2010. They have also been signed off by the Chair of JPAC and posted on the JPAC and HPA websites.*

### 5.2 **Estimates of the frequency (or risk) of HBV and HCV potentially infectious surgical bone donors being missed by testing, England 2003 – 2008 – JPAC 10-42**

This paper clarified the paper presented at the last meeting (JPAC 10-05). PEH to discuss with Epidemiology Group how to present the statistics more clearly in future reports.

### **5.3 West Nile Virus (WNV) precautions for UK blood donors – JPAC 10-44**

JPAC endorsed, with minor amendment to the wording, the suggested triggers for the institution of any new WNV deferral areas, so that they may be automatically applied to outbreaks in any other areas.

*Post Meeting Note – Updated paper (JPAC 10-44 amended 14-07-10) circulated to JPAC 23-07-10.*

### **5.4 Response to ECDC Threat Assessment April 2010: outbreak of Q fever in the Netherlands (2007-2010) – JPAC 10-45**

JPAC endorsed the recommendation to take no action in the current situation to detect and defer donors who have recently travelled to the affected areas of the Netherlands and agreed that the issue will be kept under review, and will in any case be reviewed if information or advice is issued by HAIRS which requires deferral of donors who have recently travelled to the affected area.

*Post Meeting Note: Updated guidance received from ECDC via NG on 9 July, stating that Blood Services should "consider deferring donors for 6 weeks after returning from a Q fever epidemic area to a low prevalence area. Any such measures should only be implemented after careful consideration of the estimated risk of transfusion or cell-tissue donation-associated infection in relation to the negative impact on blood supply". This is in concordance with the risk-based approach from JPAC.*

### **5.5 SACTTI report on screening of platelet concentrates for bacterial contamination – JPAC 10-46**

This updated paper was accepted as the Working Party's recommended protocol for bacterial screening of platelets. There was a query about table 7 and PEH will ask Ty Pitt to confirm the validity of these figures.

The paper will form the basis for an entry in the next edition of the Red Book on bacterial screening.

### **5.6 Xenotropic Murine leukaemia Related Virus (XMRV): Risk Assessment v1: further information – JPAC 10-47**

This paper provided further information from the European Blood Alliance and the AABB on the postulated association between XMRV and CFS. It was noted that there has also been a recent publication from CDC. It was noted that no papers have yet been published which support Lombardi's findings of a link between XMRV and Chronic Fatigue Syndrome (CFS), although the AABB have now decided to exclude donors with a past history of CFS.

An expert sub-group of the NEPNEI have recently reported that there is no evidence of any public health risk to the UK population from XMRV.

JPAC noted the views of NEPNEI.

#### **5.6.1 Draft Change Notification for Chronic Fatigue Syndrome (CFS) – JPAC 10-49**

**ACTION**

JPAC approved this change on the grounds of donor safety for whole blood and blood component donors only, with a possible implementation date of 1 October 2010. **Action:** SB and CJS

*Post Meeting Note: Change Notification No 8 2010 – Chronic Fatigue Syndrome (with an implementation date of 1 November 2010) was issued on 1 September 2010.*

**5.7 Human T-cell Lymphotropic Virus (HTLV) I and II testing of Fresh Frozen Plasma – JPAC 10-48**

HTLV screening of fresh frozen plasma is on the SaBTO workplan and will be discussed at its October meeting. JPAC is content with the evidence that it is not transmitted by frozen plasma components, whether or not they are pathogen inactivated, and, pending the outcome of the review by SaBTO, will issue changes to the Red Book.

SM

**5.8 Working Party on vCJD**

PEH informed JPAC that the SACTTI Working Party on vCJD has now been disbanded. Several groups providing advice on prions, including the WP on vCJD, have been incorporated into the Prion Working Group chaired by Prof Marc Turner.

The responsibility for the vCJD risk assessment and position statement needs to be clarified by the UK BTS Forum (UKF).

PEH will write to Marc Turner asking him to continue as member of SACTTI and also asking him to clarify with the UKF whether or not JPAC should be still responsible for the CJD position statement and risk assessment.

*Post Meeting Note: Marc Turner will continue as a member of SACTTI and has confirmed that the PWG will be responsible for both the Position Statement and the Risk Assessment on vCJD.*

**5.9 SACTTI Membership – JPAC 10-61**

PEH had written to the Chair of JPAC (JPAC 10-61) regarding the membership of SACTTI. A number of long serving SACTTI members are due to retire, with no immediate chance of replacement with candidates with equal expertise and this will impact on the committee's ability to respond to future requests from JPAC.

JPAC noted the content of PEH letter and although this cannot be solved immediately it was agreed that it was good to raise the issue.

**6. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**

**6.1 Draft Change Notification for Chronic Fatigue Syndrome (CFS) – JPAC 10-49**

See item 5.6.1 above.

**7. STANDING ADVISORY COMMITTEE ON TISSUES**

**ACTION****7.1 Long term storage of tissue products (v1) – JPAC 10-50**

SM welcomed PY to his first JPAC meeting as interim Chair of SAC Tissues.

After a long discussion JPAC approved the proposals for extension of expiry date of frozen products as specified in the paper, with a recommendation that tissue services examine the feasibility of collecting outcome data to backup the shelf life and conditions of storage. Help with a literature review could be sought from Carolyn Dorée at Systematic Review Initiative. CJS will send PY the appropriate literature review request form. SM will take to the next UK BTS Forum meeting on 24 September.

*Post Meeting Note: This was approved at the UK BTS Forum meeting on 24 September 2010.*

**8. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS****8.1 Monitoring of Factor VIII in plasma**

Graham Rowe from the Welsh Blood Service submitted a paper to the MHRA Blood Consultative Committee in March 2010 outlining the problems with using the BSQR quality monitoring parameters for FFP. The Blood Consultative Committee asked that the statement should be consolidated and sanctioned by the UK Blood Services before full discussion at the Blood Competent Authorities meeting. MHRA raised the issue as a problem statement at the Competent Authorities meeting in April 2010 with a view to full discussion at the following meeting. SACBC have therefore agreed to revise the paper and will submit to JPAC in November. **Action: CP.**

CP

**9. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY****9.1 Blood and Blood Components in Terminology (SNOMED)**

A draft paper for comment has been received by SM and LL, the purpose of which is to provide a description of the plans NHS Connecting for Health has for the population of blood and blood components within the SNOMED-CT UK Drug Extension. This appears to have been in circulation from 2005, although has not previously been seen by JPAC, and comments are requested by 31 July.

On initial review LL felt that this may well impact on the National portfolio and order systems and SACIT should engage in the consultation process. One of the suggestions put forward by the authors was that there should be a workshop and LL would support this.

LL will write a response to the consultation to be sent in conjunction with SM.

LL &amp; SM

**NAW left the meeting at 15:00 and CP left the meeting at 15:15**

**10. UK BTS FORUM JPAC 10-51****Feedback from the last UK BTS Forum Meeting on 18 June 2010 - JPAC 10-51**

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

1. Prion Working Group
2. UK Stem Cell strategic review
3. Acupuncture
4. Proposal to rename JPAC
5. NHSBT blood donor travel survey

PEH asked for it to be noted that it was NHSBT and not SACTTI that had commissioned the NHSBT blood donor travel survey.

**JM and LL left the meeting at 15:30**

## 11. **JPAC / SAC INFORMATION**

### 11.1 **Name change of JPAC – JPAC 10-52**

A change to the name of JPAC, to reflect the changes at NIBSC, was approved at the UKBTS Forum on 18 June. JPAC will now be known as the Joint UKBTS/HPA Professional Advisory Committee.

### 11.2 **Revised SAC Terms of Reference – JPAC 10-53**

Updated ToRs for each SAC were tabled. SM asked chairs to look at their relevant ToR and send any comments/amendments to CJS by 20 August.

*Post Meeting Note: Comments were received from SAC Chairs and revised Terms of Reference were submitted to the UK BTS Forum meeting on 24 September 2010.*

### 11.3 **Reintegration of SAC on Stems Cells into the SAC on Tissues**

JPAC approved the reintegration of the SAC on Stem Cells with the SAC on Tissues. It was agreed that this committee will now be known as the SAC on Tissues and Cellular Therapy Products (SAC-TCTP).

### 11.4 **JPAC Work Plan – JPAC 10-54**

The draft JPAC work plan was presented which was derived from individual SAC work plans. SM asked SAC Chairs to review, confirm accuracy and fill in any blanks within the next 2 weeks.

*Post Meeting Note: Comments were received from SAC Chairs and a revised JPAC workplan for 2010/11 was submitted to the UK BTS Forum meeting on 24 September 2010.*

### 11.5 **Feedback on JPAC Website Manager Post**

The job description has been finalised (*Post Meeting Note: Banded as grade 6 under AfC*). However because of the current recruitment freeze we will not be able to fill this post as planned in the immediate future. SM to discuss with HR and find out what options are available.

**SM**



**12. SaBTO**

LW gave an update from the SaBTO meeting on 6 July.

Items discussed were:

- Licensing of fibrinogen concentrate in progress – licence could be granted by September.  
*Post Meeting Note: Fibrinogen concentrate has been licensed for use in congenital hypofibrinogenaemia.*
- Report on 80% platelets - no Service is achieving this consistently and there is no push to go above 80%.
- Consent had gone out to consultation - divided equally, no clear consensus. Some work still to do. Any recommendations will be subject to pilots.
- Review of blood donor selection – the blood donor selection steering group has been set up, the scope approved and has held its first meeting. Implications for tissues will be the subject of a follow-up report.
- A public meeting will be held on marginal donors of organs for transplantation towards end of October.
- Draft SaBTO work plan to include:
  - HTLV testing of plasma
  - CMV negative platelets
  - Cryoprecipitate

**13. EUROPE****13.1 Competent Authorities on blood and blood components meeting 12-13 April 2010 – Summary Report – JPAC 10-55****13.1.1 Maximum pH levels for platelets at end of shelf life**

It was noted that the committee concluded that it was not justified to maintain the upper pH limit as laid down in the EU Directive. However this will require a future amendment to the Directive (and BSQR) and the committee made no commitment on time.

**13.1.2 Protein levels in donors blood**

A submission from Denmark suggested including a lower limit to the number of plasmapheresis procedures per year, below which protein levels do not need to be measured. The committee concluded that this was outside the direct remit of the directive and should be discussed within EDQM. SM agreed to take to GTS group.

*Post meeting Note: SM has written to Cees van de Poel asking if this could be raised at the next GTS meeting.*

**13.1.3 Testing of fresh frozen plasma**

See item 8.1

**13.1.4 Q Fever outbreak in the Netherlands**

See item 5.4

**13.2 CD-P-TS symposium on “implementation of pathogen reduction / inactivation technologies for blood components”, 2-3 September 2010 – JPAC 10-56**

SM has been asked to represent the UK at this symposium and give a short presentation on the current status of PI implementation in the UK and the regulatory requirements.

**14. ANY OTHER BUSINESS****14.1 Donor Selection Guidelines**

A question has been raised as to whether the Tissue Donor Selection Guidelines are going to be updated in line with the Blood Donor Guidelines. It was noted that there was no change to the underlying guidance in the DSG for blood and blood components. The other DSGs will be amended when resource allows.

**14.2 Consent for Transfusion**

The recent consultation on consent for transfusion has raised the issue of how we notify patients of the risks. This may require the development of product label/literature along the lines of pharmaceutical products issued with each unit. SM to discuss with Catherine Howell.

**SM****14.3 Human Tissue Authority (HTA)**

It was agreed that we should invite a representative from the Human Tissue Authority (HTA) to join JPAC. The Chair will send an invitation to Ms Imogen Swan, Head of Regulation, at the HTA.

*Post Meeting Note: Dr Christiane Niederlaender, Regulation Manager, Human Tissue Authority, will be representing the HTA on JPAC.*

**The meeting concluded at 16:15**

**15. DATE & VENUE FOR FUTURE JPAC MEETINGS****2010**

- Thursday 11 November - Association of Anaesthetists, London

**2011**

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