

## Joint UKBTS/HPA Professional Advisory Committee

### Minutes of the 47<sup>th</sup> meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 11<sup>th</sup> November 2010

**Meeting Commenced at: 11:05**

#### **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
Prof Ian Franklin	<b>(IMF)</b>	- Medical Director, Scottish National Blood Transfusion Service
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
Dr Richard Jones	<b>(RJ)</b>	- Medical Director, Welsh Blood Service
Mrs Linda Lodge	<b>(LL)</b>	- Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	<b>(SM)</b>	- Professional Director of JPAC (Chair)
Dr Joanne Murdock	<b>(JM)</b>	- Acting Medical Director, Northern Ireland Blood Transfusion Service
Dr Christiane Niederlaender	<b>(CN)</b>	- Human Tissue Authority (HTA)
Dr Chris Prowse	<b>(CP)</b>	- Standing Advisory Committee on Blood Components
Miss Caroline Smith	<b>(CJS)</b>	- JPAC Manager (Minute taker)
Dr Lorna Williamson	<b>(LW)</b>	- Medical Director, NHS Blood and Transplant
Dr Nay Win	<b>(NW)</b>	- Standing Advisory Committee on Immunohaematology
Dr Phil Yates	<b>(PY)</b>	- Standing Advisory Committee on Tissues
Prof Maria Zambon	<b>(MZ)</b>	- Director, Centre for Infections, Health Protection Agency (HPA)

SM welcomed Dr Christiane Niederlaender (HTA) and Prof Maria Zambon (HPA) to their first JPAC meeting. SM also informed the group that Dr Willy Murphy is moving to the Health Service Executive in Ireland in January 2011 for a 3 year programme, he had unfortunately had to send his apologies for this meeting. SM will write to WM and thank him for his input to JPAC. Prof Ian Franklin is retiring as Medical Director of SNBTS and has taken on the role of National Medical Director of the Irish Blood Transfusion Service for the next 3 years. SM invited Prof Franklin to continue as a member of JPAC in his new role.

#### **Action**

1.

#### **APOLOGIES**

Dr Willy 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 Derek Norfolk	<b>(DN)</b>	- Standing Advisory Committee on Clinical Transfusion Medicine

**Action**

Dr Nick Watkins (NAW) - Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)

**2. MINUTES OF THE LAST MEETING HELD ON 8 JULY 2010 – JPAC 10-63**

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

- Item 5.1, second paragraph, amend to say “The latest figures include ..... which has picked up 4 infections in long-term donors (2 acute and 2 chronic).”
- Item 5.9, second sentence amend to say “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.”

**3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 10-64**

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

A query had been raised from SNBTS with regard to the entry in the DSG for pregnancy.

As requested SM had discussed this issue with NG. This is now being taken forward by SACCSD and will be discussed at their next meeting.

**Bruce Cuthbertson arrived at 11.15**

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

LL met with Gifford Batstone, from the Royal College of Pathologists (RCP) and discussed the work creating the National Library of Medicine Catalogue (NLMC) and the Product portfolio with regard to the coding of components. One of the RCPs technical team has asked for a demonstration of the portfolio which LL has agreed to facilitate. They have also agreed to keep each other appraised of developments with a view to sharing information and avoiding unnecessary duplication and effort.

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

A meeting as been arranged on Tuesday 18 January at SNBTS to take this forward. Attendees will include SM, BC, CP, LL and CJS.

**3.4 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 4.1**

There had been a delay in starting a trial at the Welsh Blood Service (WBS) regarding investigating antibody titres of IgM and IgG in group O blood donors, in order to establish the required dilution for an IgG anti-A/B test and to identify

**Action**

the level of product likely to be affected. WBS confirmed that they will be starting the trial this month. The study will take about 4-5 months and the results will be brought back to JPAC. **Action:** NW

NW

SM discussed the issue of the option to reduce the risk of haemolysis from ABO incompatible platelets with the Analytical Steering Group. NHSBT are reviewing platelet provision and SM will discuss this further with Gerry Gogarty.

SM

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 the meeting on 18 January – see item 3.3.

**3.5 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 – item 5.2**

The action was for PEH to discuss, with Epidemiology Group, how to present the statistics in future reports. Due to staff shortages within this group this will be deferred until a later date and taken off the JPAC “Actions” list.

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

HTLV screening of fresh frozen plasma was discussed and approved at the SaBTO meeting on 26 October.

An instruction will come to NHSBT from the Department of Health and following this the change will need to be incorporated in the new edition of the Red Book, both in the microbiology and component specifications chapters.

SM will liaise with Nick Watkins about the DH instruction.

*Post Meeting Note: LW (NHSBT) has received a letter from Dr Rowena Jecock Lead, Blood Safety and Supply (dated 24-11-10) which states:*

“SaBTO has endorsed JPAC’s assessment and agrees that the requirement to screen frozen plasma components should be removed if they are sourced independently from cellular components. This endorsement has been made on the basis of scientific evidence which indicates that frozen plasma products do not transmit HTLV.”

*A copy of this letter and covering email have been sent to the Chairs of SACBC and SACTTI for action.*

**3.7 Blood and Blood Components in Terminology (SNOMED) – item 9.1**

LL met with Emma Melhuish to discuss the potential issues for blood components if the SNOMED CT proposal was pushed forward in its current state, based on the use and future of the codabar code. The ISBT128 code structure was considered to be better suited as a starting point for the mapping to SNOMED CT. It was therefore suggested that the current codabar codes should be mapped to ISBT128 codes which in turn would be mapped to SNOMED CT. These mappings would be available via the UK Product Portfolio.

**Action**

This proposal was put to Paul Ashford The Executive Director of ICCBBA who has welcomed the approach and a meeting has been set up to agree the process going forward.

**Action:** LL will submit a paper to the next JPAC meeting on 10 March 2011.

LL

**3.8 Consent for Transfusion – item 14.2**

Consent for Transfusion has been further discussed at SaBTO and Catherine Howell has been asked to pilot different approaches on education and information. SM will liaise with Catherine Howell regarding how JPAC can help with this.

SM

**Phil Yates arrived at 11.30**

**4. STANDING ADVISORY COMMITTEE ON TISSUES****4.1. Reinstatement of ‘non-specific’ reactive tissue donors v1 – JPAC 10-65**

This item was discussed after section 5 (SACTTI items).

Reinstatement of ‘non-specific’ reactive tissue donors was agreed so long as the additional testing is done in a Reference Laboratory.

Action: PY will draft a change notification and send to CJS.

*Post Meeting Note: Change Notification No. 14 2010 – Reinstatement of ‘non-specific’ reactive tissue donors was issued on 18 January 2011.*

It was noted that a SaBTO document “Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used In Transplantation” has been out for consultation. This document is currently in final draft stage awaiting issue.

Assessment of residual risk was discussed at length and PY was asked to review a recent paper from Alan Kitchen and estimate how this change might affect residual risk.

PY

SM will consider ways in which JPAC can perform risk analysis whenever changes to current practice are proposed and will review the NHSBT’s risk assessment framework to see if this can adapted.

SM

**5. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS****5.1 SACTTI Reference and Reporting Group JPAC 10-66**

SACTTI are proposing that this sub-group should be disbanded as it has fulfilled its purposed. This was approved by JPAC. PEH will write and record SACTTI’s thanks to the Chair and Secretary.

*Post Meeting Note: PEH has written to the Chair and Secretary.*

**5.2 Dengue Virus risk assessment (4) 26-10-10 – JPAC 10-67**

**Action**

This risk assessment was discussed at length. It was noted that since submission of this paper to JPAC data had been published from studies on blood donors in Puerto Rico.

It was agreed that the risk assessment should be updated with this data; the sections relating to donor deferral should be reworded and brought back to the next JPAC meeting on 10 March 2010. **Action:** PEH  
*Post Meeting Note:* Updated paper submitted to the JPAC meeting on 10 March 2011.

There was a wide-ranging discussion on the process of decision making for the introduction of donor deferrals for infectious disease. JPAC had already agreed on the criteria for initiation of deferral with regard to WNV (JPAC 10-44 amended). MZ felt that the HPA could assist. SM will discuss this further with MZ. **Action:** SM.

SM

As previously discussed at JPAC the travel survey will be useful in assessing the impact of any changes to donor deferral guidelines.

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

This paper was a summary of the current situation up to 4 November 2010. JPAC noted the update and that the risk assessment will be revised in early 2011.

LW informed JPAC that NHSBT is funding a large study lead by Richard Tedder investigating the prevalence of carriage of XMRV. In addition Organ Donation and Transplant have followed up 20 recipients from donors with a history of CFS for 3 years and none have symptoms of CFS/ME. This work is being written up as an urgent letter to the Lancet.

LW will ask James Neuberger to send the paper to JPAC.

LW

**5.4 Reinstatement of donors who have tested repeat reactive for a microbiological assay on screening, confirmed negative by a reference laboratory (“false positive”) – JPAC 10-69**

This algorithm has been in the Red Book for many years and was originally specified by the testing subgroup of EAGA in 1985. SACTTI wanted to look again at the principle which has not been looked at since that time, apart from a reduction in the time period before a second test (from 6 months to 12 weeks).

SM asked PEH to check that this algorithm is consistent with the CoE guidance.

*Post Meeting Note:* This has been checked and is consistent with the guidance.

The proposal for reinstatement of donors was approved and the change will be incorporated in the next revision of the UK guidelines (Red Book). This paper, when updated, will go on the website as evidence.

**5.5 Donor Arm Disinfection Recommendations – Dr Ty Pitt and SACTTI Bacteria Subgroup – JPAC 10-70**

**Action**

The contents of this paper, which are a review of skin disinfection techniques, were noted. There was considerable discussion about whether definitive targets for decontamination can be defined. PEH will discuss further with Ty Pitt.

*Post Meeting Note: PEH has discussed this further with Ty Pitt and this will be incorporated in the revised chapter for the Red Book.*

6. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

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

This paper was approved with the edition of recommending retesting female donors following a pregnancy.

**NW**

The recommendation will go in the next edition of the Red Book and SB will include advice in Chapter 3 on testing of apheresis donors. This paper will go on the JPAC website as a background paper.

**NW & SB**

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

7.1. **Donor Care and Selection Chapters for the 8<sup>th</sup> edition of the Red Book – JPAC 10-72**

SB tabled a rewrite of the 4 donor care chapters now revised into 3 chapters. The rewrite is mostly to correct some outdated information and the only major change is to the donor weight and safe extra corporeal volume allowances.

**Action:** SB to write a proposal on this for approval by JPAC.

Members were asked to review these new chapters and send comments to SB by the end of November. When approved the chapters will be issued as change notification.

SM asked SB to make minor amendments to the second paragraph of the summary of the paper.

*Post Meeting Note: A paper on Donor weight and donation volumes, and JPAC 10-72 Donor Care chapters, were circulated to JPAC on 12 November. Comments were received and Change Notification No 12 2010 – Donor Care and Selection Chapters of the Red Book and Change Notification No 13 2010 – Donor Weight and Donation Volumes were issued on 17 January 2011, with an implementation date of 1 February 2011.*

8. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS**

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

This paper was submitted to the recent EC Competent Authorities meeting.

SM is meeting with representatives from the MHRA to discuss how to take this

**SM**

**Action**

forward straight after this meeting.

**8.2 Discard Limits for frequently issued blood components: A SACBC perspective for discussion with clinical colleagues – JPAC 10-74**

This paper was approved by JPAC and CP will draft a change notification. It was also noted that it would be useful for Services to be able to trace back repeated discards to donors for follow-up and CP will incorporate this into the paper and the change notification.

**CP**

**RJ left the meeting at 14.56**

**8.3 Use and naming of Platelet Additive Solutions (PAS) – JPAC 10-75**

CP and LL will discuss further and bring back to the next JPAC meeting on 10 March 2011.

**CP and LL**

**8.4 Transport temperature for red cells – JPAC 10-76**

Tabled for Information.

**8.5 Update on Factor IX assays and exchange units – JPAC 10-77**

This is in the draft chapter for the next edition of the Red Book.

**8.6 JPAC Position Statement on Granulocyte Therapy – JPAC 10-78**

The update of the Granulocyte Therapy position statement was approved.

*Post Meeting Note: Updated JPAC Position Statement on Granulocyte Therapy was posted on the JPAC website on 15 December 2010.*

There was further discussion about the specification of the pooled granulocyte component and although this has already been issued it was noted that amendments were required. This will therefore be reissued.

*Post Meeting Note: Amended Change Notification No 7 2010 – Granulocytes, pooled, buffy coat derived, in platelet additive solution and plasma was issued on 18 January 2011.*

There was 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. **Action:** CP to take this forward.

**CP**

**PEH, PY and JM left the meeting at 15:00**

**9. JPAC WEBSITE TRANSFUSIONGUIDELINES.ORG.UK**

**9.1 Results of the Red Book Survey – JPAC 10-79**

Tabled for information.

**9.2 Website Statistics – JPAC 10-80**

Tabled for information

**Action****9.3 Website Manager Post – update**

On the advice of NHSBT Recruitment this vacancy was advertised internally within NHSBT. No interest was expressed in the post.

It was agreed that this is an important post and SM to investigate the route for regrading and external advertising.

**SM****10. RED BOOK – 8<sup>TH</sup> EDITION****10.1 Progress report**

SM asked SAC Chairs for their chapters by the end of December 2010.

**SAC Chairs****10.2 How do we make changes – do they come to JPAC?**

SM considers that any significant changes that are made in the rewrite of Red Book chapters should come to and be approved by JPAC as happens with change notifications.

**11. SaBTO****11.1 Report from Dr Nick Watkins – JPAC 10-81**

LW informed JPAC that the SaBTO group on MSM is still sitting and may have a preliminary report in January 2011.

Next years workplan for SaBTO includes the need for CMV testing and they are also looking at the Tissue Donor Selection Guidance.

**12. UK BTS FORUM JPAC****12.1 Feedback from the last UK BTS Forum Meeting on 24 September 2010 - JPAC 10-82**

Tabled for information.

**13. EUROPE****13.1 Programme and Executive Summary of EDQM Symposium on “Implementation of pathogen reduction / inactivation technologies for blood components”, Strasbourg, 2-3 September 2010 – JPAC 10-83**

This paper was tabled for information. SM has electronic versions of all the presentations and presenters are to be asked for permission to circulate more widely.

**13.2 16<sup>th</sup> Edition of the CoE Guide to the preparation, use and quality assurance of blood components**

The 16<sup>th</sup> Edition of the guide is now in draft and will be published in 2011.

**Action****14. ANY OTHER BUSINESS****14.1 Guidance for heart valve donors**

LW noted that NHSBT is now planning to collect valves from organ donors which until now went to non NHSBT banks and there is concern that our stricter donor selection guidance may lead to a shortage of valves.

It was noted that SaBTO is also going to look at tissue donor selection guidance.

**14.2 Blood Regulation Forum in Europe**

SI informed JPAC that there is a World Health Organization (WHO) Blood Regulators Network, which was established in 2006, that does not have any UK input.

Information can be found on their website:  
[www.who.int/bloodproducts/brn/en](http://www.who.int/bloodproducts/brn/en).

**LL left at 15:30**

**The meeting concluded at: 15:36**

**15. DATE & VENUE FOR FUTURE JPAC MEETINGS****2011**

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