

Joint UKBTS Professional Advisory Committee

Minutes of the 57th meeting held at the
Association of Anaesthetists, 21 Portland Place, London,
on Thursday 20th March 2014

Meeting commenced at: 11:00 am

Present

Dr Susan Barnes	(SB)	- Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	(RC)	- Standing Advisory Committee on Blood Components
Mr David Carter	(DC)	- Medicines & Healthcare products Regulatory Agency
Dr Stephen Field	(SF)	- Medical Director, Welsh Blood Service
Mrs Joan Jones	(JJ)	- Representing the Quality Managers of the 4 UK Blood Services
Dr Alan Kitchen	(AK)	- Standing Advisory Committee on Transfusion Transmitted Infections
Dr Richard Lomas	(RL)	- Representing the Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Sheila MacLennan	(SM)	- Professional Director of JPAC (Chair)
Dr William Murphy	(WM)	- National Medical Director, Irish Blood Transfusion Service
Dr Derek Norfolk	(DN)	- Standing Advisory Committee on Clinical Transfusion Medicine
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

SM informed the group that this would be Dr Derek Norfolk's last JPAC meeting and thanked Derek for all his hard work as Chair of the SAC on Clinical Transfusion Medicine since May 2005, especially the production of the 5th Edition of the Handbook of Transfusion Medicine.

This would also have been Dr Phil Yates' last JPAC meeting as Chair of the SAC on Tissues and Cellular Therapy Products, but unfortunately he was not able to attend. Phil has been a member of the SAC on Tissues since 2002 and in 2011 became Chair of the amalgamated SAC on Tissues and SAC on Stem Cells now known as the SAC on Tissues and Cellular Therapy Products.

SM welcomed Dr Richard Lomas, representing SACTCTP, to the meeting and also welcomed back Dr William Murphy, National Medical Director of the Irish Blood Transfusion Service, who has returned following work on a 3 year programme for the Health Service Executive in Ireland.

ACTION

1.

Apologies

Mr Andrew Broderick	(AB)	- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Stephen Inglis	(SI)	- Director, National Institute for Biological Standards and Control
Dr Julia Jenkins	(JJen)	- Human Tissue Authority (HTA)
Mrs Linda Lodge	(LL)	- Standing Advisory Committee on Information Technology
Dr Kieran Morris	(KM)	- Medical Director, Northern Ireland Blood Transfusion Service
Prof James Neuberger	(JN)	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant

ACTION

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|-------------------|-------------|--|--|
| Prof Marc Turner | (MT) | - Medical Director, Scottish National Blood Transfusion Service | |
| Dr Phil Yates | (PY) | - Standing Advisory Committee on Tissues and Cellular Therapy Products | |
| Prof Maria Zambon | (MZ) | - Director, Centre for Infections, Health Protection Agency (HPA) | |
2. Minutes of the last meeting held on 14 November 2013 – JPAC 14-02
- The minutes were approved as a true record of the meeting.
3. Matters arising not on the agenda (Review of actions list) JPAC 14-03
- 3.1 **JPAC Decision Making Framework – JPAC 13-23 – item 3.2**
- As the SAC Chairs have been very busy with proofing the content of the new website the progress with the framework has been slow. SM asked AK to put the HTLV paper through the framework for the next meeting and also asked SAC Chairs to look out for any appropriate items which could be put through the process.
- All SAC Chairs
- 3.2 **Eurocet 128 – JPAC 13-46 – item 3.5**
- Article 25 of the Tissue Directive (2004/23/EC) of the European Parliament refers to the formation of a single European coding system to provide information on the main characteristics and properties of tissues and cells.
- JPAC 13-46 Eurocet 128 was submitted to JPAC in July 2013, where it was noted that this is a very complex issue. It was agreed that SACTCTP and SACIT should set up a small working group, lead by Phil Yates and including HTA representation. This group would bring a paper of action points back to JPAC.
- SM asked RL to ask Dr Akila Chandrasekar, the new Chair of SACTCTP, to take this forward.
- RL
- 3.3 **Draft re-writing of Whole Blood and Components Donor Selection Guideline entries – JPAC 13-61 – item 4.1**
- Work in progress.
- SB
- 3.4 **Complementary Therapy Entry in the Bone Marrow & PBSC Donor Selection Guidelines and the Cord Blood Donor Selection Guidelines – JPAC 13-69 – item 5.3**
- See item 4.3
- 3.5 **SACTTI HTLV discussion paper: Review of HTLV testing within the UK Blood Services 2013 – JPAC 13-75 – item 6.1**
- JPAC 13-75 was submitted to the last JPAC meeting. The paper reviewed the current situation within the 4 UK Blood Services, taking into account results of 11 years of testing.
- AK is updating the paper to specifically look at the 4 options for HTLV testing of UK blood donations. These options are:
- 1) Minipool HTLV test all donations in pools of up to 48 donations (current/previous system)
 - 2) Individual HTLV test on selected (previously untested) donors

ACTION

- 3) Individual HTLV test all donations
4) Withdraw HTLV test

This paper will go to the next SACTTI meeting for comment and approval and then come back to JPAC.

AK

It was noted that HTLV testing was introduced following an MSBT instruction in 2001 and therefore any decision to change would need to be reviewed by SaBTO.

SM asked AK to put the different options through the Decision Making Framework and bring this back to JPAC.

Action: AK

AK

4.

Standing Advisory Committee on Care And Selection Of Donors

SB thanked Jane Liston for all her hard work, over the last six months, in her role as acting Chair of the SACCSD.

4.1 **Anti Parkinson's disease drugs/ Dopamine-receptor agonists and Restless legs syndrome – JPAC 14-04**

This paper is an amended version of JPAC 13-39 which was submitted to the last meeting.

JPAC approved the additional information, which was for clarification, in the entries for Central Nervous System Disease and Accept. A change notification will be issued.

Post Meeting Note: Change Notification No 20 2014 – Central Nervous System Disease was issued on 09-05-14.

4.2 **Autoimmune Disease – JPAC 14-05**

JPAC approved the recommendation that the Autoimmune Disease topic is amended to include advice regarding the use of disease but not immune modifying medication such as Sulfasalazine and Hydroxychloroquine as maintenance treatment for Rheumatoid Arthritis. A change notification will be issued.

Post Meeting Note: Change Notification No 19 2014 – Autoimmune Disease was issued on 9 May 2014.

4.3 **Complementary Therapy – JPAC 14-06**

JPAC approved the recommendation that the Complementary Therapy entry is updated to include the new name Health and Care Professions Council (HCPC) and the additional professions regulated by this council which are Hearing Aid Dispensers, Practitioner Psychologists and Social workers in England. It was noted that this will also apply to the Tissues Donor Selection Guidelines. Change notifications will be issued.

RL

Post Meeting Note: Change Notification No 21 2014 – Complementary Therapy (WB DSG) was issued on 9 May 2014.

4.4 **Interstitial Cystitis (IC) – JPAC 14-07**

SB informed the group that there is no current guidance in the WB DSG for Interstitial Cystitis.

ACTION

JPAC approved the recommendation to change the name of the current topic Kidney Disease to Kidney and Bladder Disease, with an additional section for Interstitial Cystitis, accepting donors who are no longer under investigation, have no associated condition which would prevent donation, have not required catheterisation within the last 7 days, are asymptomatic and not requiring treatment with Pentosan polysulfate sodium.

A change notification will be issued and the paper, minus the donor history, will be posted in the Document Library of the JPAC website.

Post Meeting Note: Change Notification No 22 2014 – Kidney and Bladder Disease was issued on 9 May 2014.

4.5 **Vitamin D Supplementation (Osteopenia and Vitamin and Other Nutritional Supplements) – JPAC 14-08**

SB informed the group that increasingly people are being tested for and/or offered treatment for vitamin D deficiency and that there is a danger that donors will be deferred if on long term treatment with vitamin D supplements if we do not modify our guidance.

JPAC approved the recommendation to amend the guidance for both the topics Osteopenia and Vitamin and Other Nutritional Supplements, but asked that a link to the letter from the UK Chief Medical Officers of UK should be added to the change notification under "Additional Information".

www.gov.uk/government/publications/vitamin-d-advice-on-supplements-for-at-risk-groups

A change notification will be issued.

Post Meeting Note: Change Notification No 23 2014 – Osteopenia was issued on 9 May 2014.

4.6 **Points of Care – JPAC 14-09**

Appendix 1 of Chapter 5, Collection of a Blood Component Donation, of the Guidelines for the Blood Transfusion Services in the UK, 8th Edition, (Red Book) is a document used in NHS Blood and Transplant which has recently been updated.

JPAC noted that this information is only provided in the Red Book as an example and approved the recommendation to update Appendix 1.

A change notification will be issued.

Post Meeting Note: Change Notification No 24 2014 – Points of Care was issued on 9 May 2014.

5. | | |--| | Standing Advisory Committee on Tissues and Cellular Therapy Products | |--|

Dr Richard Lomas went through the SACTCTP papers for JPAC.

5.1 **Change of title of the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines – JPAC 14-10**

JPAC approved the recommendation to change the title from "Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines" to "Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors" to clarify that this only applies to unrelated (donor panel) donors rather than related

donors. This title should be used for both the website and pdf source files.
A change notification will be issued.

Post Meeting Note: Draft Change Notification No 29 2014 is going through the approval process.

5.2 **SARS entry in the Living Tissue Donor, Deceased Tissue Donor, Cord Blood Donor and Bone Marrow and PBSC Donor Guidelines – JPAC 14-11**

Under 'Additional Information' the link to advice from DH no longer exists. Therefore JPAC approved Option B in JPAC 14-11 for 'Additional Information' which states:

"Since 2004, there have not been any known cases of SARS reported anywhere in the world. Although the threat of SARS to public health seems to have passed, international health officials continue to remain vigilant. The World Health Organization (WHO) monitors countries throughout the world for any unusual disease activity."

A change notification will be issued.

Post Meeting Note: Draft Change Notification No31 2014 is going through the approval process.

5.3 **Monoclonal gammopathy of Uncertain Significance (MGUS) – JPAC 14-12**

JPAC approved the recommendation to bring all 4 Tissues and Cells DSGs into line with the Whole Blood DSG by including monoclonal gammopathy of uncertain significance (MGUS) as an example of a clonal disorder under the entry for Haematological Disease.

A change notification will be issued.

RL

5.4 **Male-sex-with-male - Tissue and Cell Donor Guideline Changes – JPAC 14-13**

These proposed changes translate the outcomes of the SaBTO Tissues and Cells MSM donor selection review into the four Tissues and Cells Donor Selection Guidelines.

JPAC had been advised by AB that these recommendations have been noted by the Health Ministers in England, Scotland, Wales and Northern Ireland.

It was noted that two amendments were required to bring the Tissues and Cells DSGs in line with the Whole Blood and Components DSG.

- 1) Clarify the deferral for female whose partner is MSM.
- 2) Remove the terms homosexual and bisexual

A revised version will be brought back to the next JPAC meeting.

Post Meeting Note: Draft Change Notifications Nos 32 and 34 to 40 2014, issued following the outcomes of the SaBTO Tissues and Cells MSM donor selection review, are going through the approval process.

5.5 **Steroids entry in the Cord Blood Donor Selection Guidelines – JPAC 14-14**

The use of steroids to induce fetal lung maturation is a common therapy and many donations could be lost if the guidance is not explicit. SACTCTP recommends adding the text in JPAC 14-14 to the Steroid entry in the Cord Blood Donor Selection Guidelines.

This paper was presented at the previous meeting but JPAC had some concerns

ACTION

about taking cord blood from neonates with lung problems. This revised paper clarified the safeguards put in place to prevent harm. JPAC approved the recommendation and a change notification will be issued.

Post Meeting Note: Draft Change Notification No 33 2014 is going through the approval process.

6.

Standing Advisory Committee on Blood Components

6.1 **Pathogen reduced red cell concentrates – JPAC 14-15**

The purpose of the paper was to brief JPAC on the plans for a clinical trial of pathogen inactivated red cells, to be manufactured by NHSBT and transfused at University College London Hospital (UCLH), and to seek approval of the trial component specification. This trial is due to start in the autumn of this year.

JPAC approved the specification with a few amendments, as below, the specification will be put into the Trial Components section on the new website. SaBTO have requested that the UKBTS develop a framework for evaluating new/changes to PI systems for platelets as was developed for the assessment of prion filters. This needs to be added to both the SACBC and SACTTI workplans.

A3.2.1. Technical information – 2nd and 3rd bullet points

- Provided the pathogen reduction system CE mark states that it may be used as an alternative to irradiation to prevent transfusion-associated graft versus host disease, irradiation of the component is not required.
- Provided the pathogen reduction system CE mark states that it may be used as an alternative to serological testing for the prevention of transfusion-associated CMV infection, CMV testing of the component is not required.

Component Code Request Form

Label Text

Component Description line 1 Red Cells in Additive Solution for Pathogen Inactivation trial
Component Description line 2 LEUCOCYTE DEPLETED –
TRIAL ARM A

Post Meeting Note: JPAC 14-15 Amended – Pathogen reduced red cell concentrates was circulated to JPAC on 21 March 2014 and Change Notification No 17 2014 – Red Cells in Additive Solution, Leucocyte Depleted, Pathogen Reduced was issued on 7 May 2014. This specification now appears in Annex 3 of the Red Book on the JPAC website.

7.

Standing Advisory Committee on Immunohaematology
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7.1 **Guidelines for the Blood Transfusion Services in the United Kingdom, Chapter 12 (Donation Testing), Section 12.11.3 Additional Phenotyping – JPAC 14-16**

This paper was originally submitted to JPAC in 2012 and, at the request of the Chair of JPAC, has now been amended and resubmitted to reflect risk estimates expressed in a format consistent with microbiological assessments i.e. per million.

NW was congratulated on this paper and was encouraged to publish this work.

8.

Standing Advisory Committee on Transfusion Transmitted Infections

8.1 **JPAC Position Statement - The estimated risk that a donation entering the blood supply is a potentially infectious window period donation: risks specific for HBV, HCV and HIV in the UK – JPAC 14-17**

JPAC approved the updated estimates, noting that the risk is slightly decreasing across the board. CJS will update the JPAC Position Statement which appears on the JPAC website.

Post Meeting Note: The updated version of this position statement was posted on the JPAC website on 23 April 2014.

9.

SaBTO update

In the absence of Andrew Broderick LW gave the SaBTO update.

Minutes from the last meeting on 3 December 2013 are not yet available. The next meeting is due to take place on Tuesday 29 April and will be preceded on Monday 28 April by an open meeting focusing on advanced cellular products.

The future workplan includes:

- Report from the Working Group on Hepatitis E in 2015
- Donors from Sub-Saharan Africa

There was a discussion about the increasing concern regarding the issue of the increase in geographical spread of viral disease and reduction in areas of the world affected by malaria and its implications for travellers. It was suggested that SM should raise this with SaBTO.

SM

10.

Patient Safety: New EU Rapid Alert platform for human Blood and Blood Components
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10.1 DC informed JPAC that the Rapid Alert system for human blood and blood components (RAB) was introduced by the European Union (EU) in February. The purpose of the RAB is to provide the competent authorities of the EU, European Economic Area (EEA) countries and the European Commission with an effective and secure network tool for the exchange of information on urgent measures, to ensure the safety of human blood and blood components for transfusion.

11.

JPAC website transfusionguidelines.org.uk

11.1 **Redevelopment of the JPAC website – update – JPAC 14-18**

SM informed the group that Darren Elvidge, Website Manager, had left JPAC at the end of January. CJS & SM have been working closely with National Services Scotland (NSS) IT and the software company Target, to complete delivery of the new website.

The planned date for completion and launch is 31 March 2014.

Quality Management requirements are being given high priority and final approval of the content for each area of the website by its 'owner' will be documented on the Project Plan, which has been document controlled within QPulse.

Post Meeting Note:

JJ has informed the Quality Managers of the 4 UK Blood Services of the go live date

of 31 March 2014. The website went live on Monday 31 March.

12. UK BTS Forum

12.1. **Report back from the UK BTS Forum meetings on 6 December 2013 and 14 March 2014 – JPAC 14-19**

SM reported back from the last two UK BTS Forum meetings which took place on 6 December and 14 March.

- Acupuncture donor deferral criteria - A study protocol written by the joint NHSBT/PHE epidemiology team has been approved.
- Duration of blood donation archive sample storage - This paper was reviewed and it was agreed to maintain the current arrangements.
- Feedback from CD-P-TS meeting - It was noted that SM had been elected Chair of the CD-P-TS and that Dr Pat Hewitt had been elected the UK representative.
- Proposal for JPAC support - The UK Forum approved a proposal for future staffing support for JPAC following the departure of the JPAC Website Manager.
- House of Commons Select Committee Inquiry into Blood, Tissue and Organ screening and vCJD - This inquiry was launched in December 2013 and SM, as Chair of JPAC, was asked to give oral evidence on 5 February. Written evidence and transcripts from the oral sessions can be found on the website inquiry page at:

<http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2010/blood-tissue-and-organ-screening/>

13. Any Other Business

13.1 **Look back and Trace back – JPAC 14-20**

SF tabled a short paper which defined the terms Look back and Trace back.

It was agreed that these definitions were useful and that they could be circulated further via the website, Quality Managers, SACCS, Medical Directors and MHRA.

Post Meeting Note: DC reported back that the MHRA had further questions about these definitions and they will therefore be amended prior to further circulation. We are awaiting confirmation from the MHRA that they are happy with the revised proposed definitions.

Action: DC

DC

13.3 **Alliance of Blood Operators: Overview of Risk-Based Decision Making (RBDM) from Donor to Recipient – PowerPoint presentation**

LW went through this presentation for JPAC. This was an introduction to a consultation due to take place between March and June 2014.

Project Mandate: To develop an integrated, internationally applicable risk framework, entrenched in donor safety and optimal patient outcomes, to guide major policy and operational change.

It was agreed that it would be useful to see the questions to help decide who would be most the appropriate people to respond to the consultation. **Action:** LW

LW

Post Meeting Note: Presentation was circulated to JPAC on 21 March 2014.

14.

Date & venue for future JPAC meetings

2014

- Thursday 17 July - The Association of Anaesthetists, London
- Thursday 13 November - The Association of Anaesthetists, London

2015

- Thursday 12 March - The Association of Anaesthetists, London
- Thursday 18 June - The Association of Anaesthetists, London
- Thursday 12 November - The Association of Anaesthetists, London

Meeting closed at: 13:57