APPROVED 14/11/2013

Joint UKBTS Professional Advisory Committee

Minutes of the 55th meeting held at the
Association of Anaesthetists, 21 Portland Place, London,
on Thursday 4 July 2013

Meeting commenced at: 11:00

Present

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Mr Andrew Broderick	**(AB)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
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
Prof Ian Franklin	**(IMF)**	-	National Medical Director, Irish Blood Transfusion Service
Dr Victoria Gauden	**(VG)**	-	Human Tissue Authority (HTA)
Dr Patricia Hewitt	**(PEH)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Mrs Joan Jones	**(JJ)**	-	Representing the Quality Managers of the 4 UK Blood Services
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
Dr Phil Yates	**(PY)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Jane Liston	**(JL)**	-	Member of SACCSD (Observer)

SM welcomed Mr David Carter to his first JPAC meeting, DC has taken over from Mr Nigel Goulding as the MHRA representative on JPAC, and Dr Jane Liston, member of SACCSD, who was attending as an observer.

SM informed JPAC that this was Dr Pat Hewitt's last JPAC meeting and the committee thanked PEH for all her hard work as Chair of SACTTI since 2006.

ACTION

1. Apologies

Prof James Neuberger	**(JN)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Prof Marc Turner	**(MT)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Health Protection Agency (HPA)

2. Minutes of the last meeting held on 21 March 2013 – JPAC 13-37

The minutes were accepted as a true record of the meeting with one minor correction to item 5.2.

ACTION

3. Matters arising not on the agenda (Review of actions list) JPAC 13-38

3.1 **Babesia risk assessment v2 - JPAC 12-58 – item 3.2**

It had been agreed at a previous JPAC meeting that it would be useful for SACTTI to develop a spreadsheet / dashboard of potential emerging infections that may have implications for transfusion with indications of level of risk to inform JPAC.

SACTTI had noted that this would require a lot of resource and therefore would not take this forward at this time. Closed.

3.2 **Chikungunya Virus risk assessment v4 - JPAC 12-59 – item 3.3**

SI had informed JPAC, at the meeting in November, that the World Health Organisation (WHO) have a new blood regulators network set up.

SI has made further enquiries and this is unlikely to be of relevance to JPAC.

3.3 **Chapter 13: Donation testing (red cell immunohaematology) 13.11.3 Additional Phenotyping – JPAC 12-70 – item 3.5**

At a previous JPAC meeting SACIH were asked to present the risk assessment calculations in a similar way to those in SACTTI papers, in a revised paper for the next JPAC meeting for consistency in approach, but agreed that the change to testing requirements to enable labelling with phenotype information could go ahead. SM and NW have already discussed the matter and NW will submit a paper to the next JPAC meeting in November. NW

3.4 **Reinstatement of donors who are detected with acute HBV infection at the time of blood donation - JPAC 13-11 – item 5.1**

PEH has promulgated this information through the Transfusion Microbiology Clinical Group. Closed.

PY and IF arrived at 11:10

3.5 **Novel Coronavirus infection - JPAC 13-12 – item 5.2**

On agenda.

3.6 **Excipient murine retroviruses - JPAC 13-15 – item 5.5**

JPAC had asked VG to raise this issue at the HTA and feed back.

The HTA licences 5 stem cell derivation centres at present. All centres are currently working towards using alternatives to mouse feeder cells (xeno or feeder free cultures). There is nothing specific in the European Union Tissue and Cells Directives (EUTCD) that prevents the use of mouse feeder cells. Although it is unlikely that any newly derived stem cells lines will be cultured with mouse feeder cells, a number of historical stem cell lines intended for human use may have been co cultured with mouse feeder cells. As advanced therapy medicinal products (ATMPs), these cell lines will require clinical trial / marketing authorisation from the MHRA. This process will include comprehensive characterisation of any feeder cells used as raw materials and a safety evaluation of any adventitious agents. Direct viral testing for known murine viruses (e.g. XMRV) would be part of this.

3.7 **UK Blood Services blood component leucocyte depletion - JPAC 13-21 – item 3.2**

JJ has circulated this paper to the UK Quality Group, the UK Quality Managers and

ACTION

their Quality Monitoring sub-group.

The possibility of producing a JPAC Position Statement had been discussed at JPAC and RC agreed to take this back to SACBC for consideration. This was discussed at the last SACBC meeting where it was noted that most of the relevant information was available in the 8th Edition of the Red Book.

As there would be very little benefit from this extra work JPAC agreed not to take this forward.

3.8 **Pathogen Inactivation of platelets - JPAC 13-22 Confidential – item 7.3**

AB informed JPAC that SaBTO are forming a sub-group, Chaired by LW, to take this forward.

3.9 **JPAC Decision Making Framework – JPAC 13-23 – item 8**

SAC Chairs are currently trialling the framework on a couple of recent items which have been submitted to JPAC, one straightforward and one more complex issue. The outcomes will be discussed at the next JPAC Executive Working Group meeting in October. — All SAC Chairs

4. Standing Advisory Committee on Care and Selection of Donors

4.1 **Anti Parkinson's disease drugs/Dopamine-receptor agonists and Restless legs syndrome – JPAC 13-39**

JPAC endorsed the changes to the Whole Blood Donor Selection Guidelines, as per JPAC 13-39, amending the entries for Central Nervous System Disease and Accept. A change notification will be issued. — SB/JL/CJS

4.2 **Correction of the Whole Blood Donor Selection Guideline entries for Chiari Syndrome and Malformation - JPAC 13-40**

JPAC endorsed the recommendation to change Chiari Syndrome and Malformation in the Whole Blood Donor Selection Guidelines, as per JPAC 13-40 and a change notification will be issued. — SB/JL/CJS

5. Standing Advisory Committee on Transfusion Transmitted Infections

5.1 **Crimean-Congo Haemorrhagic Fever (CCHF) risk assessment – version 4 – JPAC 13-41**

PEH informed JPAC that the main changes to this risk assessment were updating the information about epidemiology and the affected countries. The main affected areas are in eastern Europe and Russia, and the current large outbreaks in Turkey and Russia are in areas not commonly visited by tourists.

JPAC endorsed the recommendation to take no specific action in the absence of any evidence of disease imported into the UK. The situation should be reviewed if there is significant change in the affected areas or if there are reports of imported cases in the UK.

5.2 **Human herpesvirus-8 risk assessment – version 4 – JPAC 13-42**

PEH informed JPAC that the risk assessment has been updated with the addition of new data and references, and a new section on HHV8 and organ transplant recipients. Information relating to tissue transplantation is lacking.

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SM stated that this was a very useful and clear risk assessment.

JPAC endorsed the recommendation to take no specific action and keep the matter under review.

5.3 **Middle East respiratory syndrome coronavirus (MERS-CoV) risk assessment – version 1 – JPAC 13-43**

Dr Kieran Morris arrived 11:36.

PEH informed JPAC that number of cases of this newly emerging infection are increasing every week. It was noted that there will be a large number of travellers from the UK visiting Saudi Arabia for the Hajj.

There are still many questions about this disease that remain unanswered, such as the period of asymptomatic viraemia, the intermediate host and deferral period for blood donation post infection.

JPAC endorsed the SACTTI advice to keep the international situation under close observation. PEH was asked to prepare a 2-weekly summary of activity for circulation to JPAC, noting any changes in affected areas.

Post Meeting Note: 2-weekly summaries of activity are being circulated to JPAC.

5.4 **Severe Acute Respiratory Syndrome (SARS) coronavirus risk assessment – version 2 – JPAC 13-44**

JPAC noted that the risk assessment had been reviewed and no changes were required.

5.5 **Deferral after possible risk of blood-borne virus exposure – JPAC 13-45**

After a long discussion JPAC agreed that no changes are required to the DSGs with regard to deferral after possible risk of blood-borne virus exposure.

6. Standing Advisory Committee on Tissues and Cellular Therapy Products

6.1 **Eurocet 128 – JPAC 13-46**

PY and LL went through this paper for JPAC.

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 noted that this is a very complex issue and, after a long discussion, it was agreed that SACTCTP and SACIT should set up a small working group, lead by PY and including HTA representation. This group would bring a paper of action points back to the next JPAC meeting in November. PY

7. Standing Advisory Committee on Blood Components

7.1 **Shelf-life (when frozen) of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP – JPAC 13-47**

SACBC have been asked to consider extending the shelf-life when frozen of FFP

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in order to maximise the plasma donations from Club 96 donors. JPAC 13-47 summarises the available data.

JPAC endorsed the recommendation that the shelf-life of frozen components be extended from 24 to 36 months at the current storage temperature of ≤ -25^{o}C and a change notification will be issued. RC

7.2 **Shelf-life of frozen plasma components following thawing – JPAC 13-48**

RC went through this paper for the group.

It was noted that there was a really good response to the questionnaire from hospitals, including medical staff.

RC noted that at SACBC there was no strong consensus on the way forward with this.

After a long discussion JPAC was also not convinced of the need for change, particularly with the lack of clinical data, on the use of extended storage of thawed FFP. It was suggested that it may be more appropriate to approach BCSH as this is a clinical issue.

Action: SM to discuss with the BCSH Transfusion Task Force.

Post Meeting Note: SM has discussed this with the BCSH Transfusion Task Force Chair who felt that this would be difficult to include in clinical guidelines.

8. Acupuncture – JPAC 13-49

SM went through this paper, which provided an update following accreditation of the British Acupuncture Council (BAcC) by the Professional Standards Authority for Health and Social Care under the new Accredited Voluntary Register scheme.

It was agreed that the accreditation of BAcC under the Professional Standards Authority's Accredited Voluntary Registration Scheme should not change the position of the UK Transfusion Services with respect to the Donor Selection Guideline for Complementary Therapy, which states JPAC considers statutory registration of practitioners to afford the best overall guarantee that blood donated by individuals who have undertaken complementary therapy is safe.

Post Meeting Note: SM has written to Mr Nick Pahl, Chief Executive of the British Acupuncture Council (05 July 2013), outlining JPAC's position, that we consider that statutory registration of practitioners afforded the best overall guarantee that blood donated by patients receiving acupuncture is safe, and that blood safety is our highest priority.

9. SaBTO update – Mr Andrew Broderick

SaBTO met on the 24th June 2013.

The MSM Tissues and Cells Donor Selection Review was formally presented.

AB summarised the recommendations which have been circulated to ministers within the four health administrations for official sanction.

He will inform JPAC when approval has been granted, so that SACTCTP can amend the Donor Selection Guidelines as appropriate.

ACTION

It was also agreed that SaBTO will reconsider data currently being collected on a novel bone processing method to remove residual cellular marrow, and consider guidance on use of NAT testing by tissue banks when next reviewed.

Bio-vigilance could be improved with better data collection. DH will facilitate a meeting with stakeholders and regulators to discuss options.

A report on the sourcing of blood from the post 1/1/96 birth cohort as a vCJD risk reduction measure was presented and discussed.
This cohort of potential blood donors are believed to be a lower risk of vCJD contaminated blood; however a concern has been raised regarding the prevalence of EBV, CMV and B19 viruses amongst this cohort. A study is proposed to determine the prevalence and seroconversion rates amongst this cohort. SaBTO were asked whether operational roll out of Club 96 plans could be undertaken simultaneously with the prevalence study but the committee felt that the safest option would be to await the outcome of the study and then complete a risk assessment.

The club 96 working group had also presented a report considering a revision of the MSBTO recommendation of 1997, that all blood products for neonatal or infant transfusion should be manufactured from second or subsequent donations. The paper identified that using first time donations would pose a small increased risk of transmission of HIV, HBV and HCV. SaBTO recommended that as the roll out of Club 96 operational plans had been placed on hold there was no urgent operational demand for this recommendation be changed. It was agreed that this issue should be revisited when the virus prevalence study was next revisited.

Ongoing SaBTO work includes:

- a review of the requirement to produce 80 % of platelets via apheresis as a vCJD risk reduction measure –due to report to SaBTO in September 2013
- a review of Pathogen Inactivation of Platelets – due to report to SaBTO in December 2013

10. JPAC website transfusionguidelines.org.uk – JPAC 13-50

SM went through this paper for JPAC which was a summary of progress of the new website.

11. UK BTS Forum

11.1 **Feedback from the UK Forum meeting on 14 June 2013**

The main JPAC items at the last UK Forum were:

- JPAC workplans 2012-13, final version and 2013/14. SM thanked the SAC Chairs for all their hard work over the last year.

- Blood Component Labelling Workshop. There was a considerable amount of discussion about how much resource would be required for this project which at present is unclear. SM agreed to circulate the survey and examples of proposed labels to the Forum, and will keep them updated on developments.

- Retirement of SAC Chairs. SM informed the UKF that 3 SAC Chairs will be relinquishing this role in the next few months – these are Dr. Pat Hewitt (SACTTI, July); Dr. Derek Norfolk (SACCTM, November) and Dr. Phil Yates (SACTCTP, March 2014) and that we will commence recruitment of

ACTION

replacements.

- New name of JPAC. JPAC was previously known as the Joint UKBTS/NIBSC Professional Advisory Committee. When NIBSC became part of the Health Protection Agency (HPA) the name of the committee changed to the Joint UKBTS/HPA Professional Advisory Committee. NIBSC is now part of the Medicines and Healthcare products Regulatory Agency alongside the Clinical Practice Research Datalink (CPRD) and not the HPA. The membership of JPAC consists of members from organisations other than the blood services - HTA, MHRA etc. which are not reflected in the title of the committee. Only the 4 UK Blood Services contribute financially to the running of JPAC. The UKBTS Forum approved the recommendation to change the name of JPAC to the Joint UKBTS Professional Advisory Committee.

12. JPAC Work Plans

12.1 **JPAC Work Plan 2012 to 2013 – Final – JPAC 13-52**

Circulated to JPAC for information.

12.2 **JPAC Work Plan 2013 to 2014 – JPAC 13-53**

Circulated to JPAC for information.

13. Any Other Business

13.1 **Extra-corporeal volume tables in the 'Red Book' 8th Edition**

SF had noted an error in appendix 1 of Chapter 3 of the Red Book Extra-corporeal volume tables.

A Change Notification will be issued. SB

14. Date & Venue for future JPAC meetings

2013

- Thursday 14 November - Association of Anaesthetists, London

2014

- Thursday 20 March - Association of Anaesthetists, London New date
- Thursday 17 July - Association of Anaesthetists, London
- Thursday 13 November - Association of Anaesthetists, London

Meeting closed at: 14:38