APPROVED 04/07/2013

Joint UKBTS/HPA Professional Advisory Committee

Minutes of the 54th meeting held at the
Association of Anaesthetists, 21 Portland Place, London,
on Thursday 21 March 2013

Meeting commenced at: 11:05

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
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)
Mr Nigel Goulding	**(NG)**	-	Medicines & Healthcare products Regulatory Agency
Dr Patricia Hewitt	**(PEH)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Joan Jones	**(JJ)**	-	Representing the Quality Managers of the 4 UK Blood Services
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
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

SM informed JPAC that Nigel Goulding is retiring from the MHRA at the end of April and thanked him for his input into JPAC since he joined the committee in March 2007.

SM welcomed Andrew Broderick (SaBTO Observer) and Joan Jones (UK Quality Managers Representative) to their first JPAC meeting.

On 1 April 2013 the Health Protection Agency (HPA) becomes Public Health England (PHE).

ACTION

1. Apologies

Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Joanne Murdock	**(JM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Prof James Neuberger	**(JN)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
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 8 November 2012 – JPAC 13-02

ACTION

The minutes were accepted as a true record of the meeting with two minor corrections.

3. Matters arising not on the agenda (Review of actions list) JPAC 13-03

3.1 **Mobilised Granulocytes – JPAC 12-38 – item 3.4**

SM had taken this paper to the GTS meeting and it was agreed that this guideline will appear in the next edition of the CoE guide due in 2 years time.

3.2 **Babesia risk assessment v2 - JPAC 12-58 – item 4.1**

It was agreed at the last 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. PEH will discuss with SACTTI. PEH

3.3 **Chikungunya Virus risk assessment v4 - JPAC 12-59 – item 4.2**

SI had informed JPAC, at the last meeting in November, that the World Health Organisation (WHO) have a new blood regulators network set up. He will contact WHO, ask which groups are doing infection monitoring, and report back to JPAC. SI

3.4 **Estimates of the frequency (or risk) of HBV, HCV and HIV potentially infectious donations entering the UK blood supply, 2010-2011 - JPAC 12-85 – item 4.8**

This was discussed with PEH after the last JPAC meeting, and she felt that the cover sheet should remain as submitted, as this explained why a previous decision by JPAC had not been followed though and to provide an audit trail. This was agreed by JPAC.

3.5 **Chapter 13: Donation testing (red cell immunohaematology) 13.11.3 Additional Phenotyping – JPAC 12-70 – item 6.1**

SACIH were asked to present the risk assessment calculations in a similar way to those in SACTTI papers, in a revised paper for JPAC for consistency in approach, but agreed that the change to testing requirements to enable labelling with phenotype information could go ahead.

A revised paper will be submitted to the next JPAC meeting in July. NW

3.6 **Notes from the National Competent Authorities for Blood meeting, 11-12 October 2012 – JPAC 12-73 – item 8**

Potential Review of the EU Directives

The paper "Proposed changes to the EU Directive on Labelling" was sent to NG on 24 January 2013 for submission to the EU for a change in the Directive. This was taken to the Blood Consultative Committee meeting on 6 March by JJ on behalf of JPAC.

It was agreed that SM will send NG a more detailed proposal.

Post Meeting Note: The paper "Proposed changes to the EU Directive on labelling" had been well received at the meeting in Brussels and is now on the list for potential changes to the Directive.

ACTION

4. Standing Advisory Committee on Care and Selection of Donors

4.1 Clarification of Donor Selection Guidelines entry for Chest Pain - JPAC 13-04

JPAC endorsed the recommendation to change the wording of the Chest Pain entry to "If the donor has been investigated for chest pain and causes that would otherwise result in deferral have been excluded such as ischaemic heart disease, pulmonary embolism or infection, accept" and a change notification will be issued.

Post Meeting Note: Change Notification No 5 2013 Chest Pain, was issued on 3 June 2013. Source files were available for training on the JPAC website on 11 June and the changes will be live on 9 July 2013.

4.2 Guidance in the Donor Selection Guidelines on Left and Right Bundle Branch Block – JPAC 13-05

JPAC endorsed the recommendation to change, for clarification, the wording of the Cardiovascular Disease entry with regard to Left Bundle and Right Bundle Branch Block and a change notification will be issued.

Post Meeting Note: Change Notification No 6 2013 Cardiovascular Disease, was issued on 3 June 2013. Source files were available for training on the JPAC website on 11 June and the changes will be live on 9 July 2013.

4.3 Guidance in the Donor Selection Guidelines on Wounds, Mouth & Skin Ulcers – JPAC 13-06

JPAC endorsed the recommendation to change, for clarification, the wording of the Wounds, Mouth and Skin Ulcers topic and a change notification will be issued.

Post Meeting Note: Change Notification No 7 2013 Wounds, Mouth and Skin Ulcers was issued on 3 June 2013. Source files were available for training on the JPAC website on 11 June and the changes will be live on 9 July 2013.

4.4 Typhoid and Paratyphoid index entries in the Donor Selection Guidelines: Addition to the "Infection – Chronic" entry – JPAC 13-07

JPAC endorsed the recommendation to change the entry for Infection – Chronic with regard to typhoid and paratyphoid and a change notification will be issued.

Post Meeting Note: Change Notification No 3 2013 Infection - Chronic, was issued on 3 June 2013. Source files were available for training on the JPAC website on 11 June and the changes will be live on 9 July 2013.

4.5 Updated Hepatitis B (HBV) guidance in the Donor Selection Guidelines – JPAC 13-08

The entry for hepatitis B (HBV) had been discussed at SACTTI and it was agreed that the guidelines for the management of donors/potential donors who have a partner with recovered HBV should be similar to those for HCV.

JPAC endorsed the recommendation to change the hepatitis B (HBV) entry and a change notification will be issued.

JPAC noted that extra training for this change would be needed and agreed that there would be a release date of 2 months in this instance to allow the Services sufficient time for staff training.

Post Meeting Note: Change Notification No 2 2013 Hepatitis B, was issued on 2

ACTION

May 2013 to allow a 2 month release date. Source files were available for training on the JPAC website on 11 June and the changes will be live on 9 July 2013.

4.6 **West Nile Virus (WNV) symptoms: deferral from donation – JPAC 13-09**

JPAC endorsed the recommendation to change the deferral from 6 months to 4 months (just over 120 days) and for clarification add further text under Discretionary 2) Donors who have been back in the UK for less than four months, who have had symptoms suggestive of WNV infection while abroad or within 28 days of return, (but no firm diagnosis of WVN infection) if a validated NAT for WNV is to be undertaken on the donated component(s), accept. A change notification will be issued.

Post Meeting Note: Change Notification No 1 2013 West Nile Virus, was issued on 24 April 13. Source files were available for training on the JPAC website on 7 May and the changes went live on 4 June 2013.

4.7 **GDRI changes consequent on the changes to the distribution of the Chikungunya Virus and Malaria – JPAC 13-10**

The risk areas of Chikungunya have not been reviewed since 2005. SACCSD have reviewed the current distribution for Malaria and Chikungunya virus and recommended a number of changes to the GDRI and that in future data should be reviewed annually.

JPAC endorsed the recommended changes to the GDRI listed on page 10 of JPAC 13-10. It was noted that SACCSD were not recommending any changes for France and Italy. A change notification will be issued.

Post Meeting Note: Change Notification No 4 2013 Chikungunya Virus, was issued on 3 June 2013. Source files were available for training on the JPAC website on 11 June and the changes will be live on 9 July 2013.

5. Standing Advisory Committee on Transfusion Transmitted Infections

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

JPAC endorsed the SACTTI recommendation to take into account HBV DNA positivity when advising on donor reinstatement after detection of an acute HBV infection in the donor. PEH will promulgate it through Transfusion Microbiology Clinical Group and CJS will do a letter to Medical Directors to draw this to their attention. PEH

Post Meeting Note: CJS wrote to the Medical Directors on 30 April 2013.

5.2 **Novel Coronavirus infection - JPAC 13-12**

Because of the recent cases of novel Coronavirus, in February this year, SACTTI wanted to draw this to the attention of JPAC. At present there is no indication that there is a threat to the UK blood supply.

JPAC endorsed the recommendation to keep the situation under review and to prepare a revised risk assessment to take account of the new developments. PEH

SM informed JPAC we have had a request from HPA to collect convalescent plasma from one of the recent cases. NHSBT are currently looking at the logistics of this, but SACBC has prepared component codes in readiness.

ACTION

5.3 **SACTTI advice regarding measles and blood donation, version 2 - JPAC 13-13**

HPA are expecting more cases of measles in 2013, but there are no documented cases of transfusion transmitted measles infection.

JPAC endorsed the recommendation that no additional donor selection measures are required in light of the current measles outbreak, and reinforce the precautionary nature of any recall initiated when a donor reports a diagnosis of measles following blood donation.

5.4 **Lymphocytic Choriomeningitis Virus (LCMV) Risk Assessment, version 3 - JPAC 13-14**

This paper had been resubmitted to JPAC, but there were in fact only a few small changes in the text and no change in the content to the paper which JPAC endorsed at the last meeting in November 2012.

5.5 **Excipient murine retroviruses - JPAC 13-15**

PEH asked JPAC to note that while the murine retrovirus concern has been closed with respect to the blood supply, there is a continuing concern in relation to stem cell expansion on murine feeder layers.

VG agreed to raise the issue at the HTA and feed back to the next JPAC meeting in July. VG

5.6 **SACTTI Risk Assessment template - JPAC 13-16**

The SACTTI risk assessment templates are completed for blood components but there are other areas like tissues, cells etc., that the blood services are involved with. SACTTI decided that they don't have the expertise for anything other than blood but felt they should include, on the new template, a prompt to highlight whether the subject may be relevant to organs, tissues and cells.

A new section 8 "Actions and Recommendations" has also been added.

JPAC approved the new risk assessment template.

5.7 **JPAC Position Statement: Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply - For information only - JPAC 13-17**

The JPAC Position Statement "Blood donor selection to minimise risk of transfusion transmissible infectious agents entering the blood supply" has been reviewed by SACTTI and the SACCSD, and updated with information from the NHSBT/ HPA Epidemiology team.

This new version has been posted in the Document Library on the JPAC website and had been submitted to JPAC for information.

5.8 **JPAC Position Statement: West Nile Virus - For information only - JPAC 13-18**

The JPAC Position Statement is updated annually and includes up to date data from USA, Canada, the EU and neighbouring countries, and results of routine donation screening for WNV RNA in NHSBT donations.

ACTION

After a couple of amendments to section 3.1 JPAC endorsed this new version which will be posted in the Document Library on the JPAC website.

Post Meeting Note: The updated version of the position statement was posted on the JPAC website on 17 April 2013.

6. Standing Advisory Committee on Tissues and Cellular Therapy Products

6.1 HTLV testing of donors of tissues and cells - JPAC 13-19

As PY was delayed PEH went through JPAC 13-19 for the group. This paper had been submitted to JPAC for information.

It was noted by JPAC that the Annexes II and III of Directive 2006/17/EC have been amended to replace the term "high incidence" with "high prevalence" in the description of endemic areas for HTLV infection. There is however no specific threshold value specified for what is considered 'high prevalence'. As all UKBTS tissue and cell donors are already routinely tested for HTLV I/II no further action is required by JPAC. There is no change to UK law.

VG informed JPAC that the changes to the Directive have been adopted by the European Commission but have not yet been transposed into UK law (transposition needs to take place by 17 June 2014). The HTA will seek clarity on thresholds of high prevalence of HTLV I/II from the European Centre for Disease Control and will issue an updated HTA position statement with respect to HTLV testing of donors for tissue products entering the UK from outside the EU.

7. Standing Advisory Committee on Blood Components

7.1 Specification for pooled methylene blue-treated cryoprecipitate - JPAC 13-20

RC went through this paper for JPAC. A specification for cryoprecipitate produced from single units of methylene blue-treated plasma is in the Red Book (Chapter 7). Hospitals have requested that this component be made available as a pooled component for larger children, rather than having to transfuse units individually.

JPAC approved this specification and a change notification will be issued.

Post Meeting Note: Change Notification No 11 2013 Pooled methylene blue-treated cryoprecipitate was issued on 27 June 2013.

7.2 UK Blood Services Blood component leucocyte depletion - JPAC 13-21

RC went through this paper for JPAC. This paper is mainly for information and it presents 3 years' of data on performance of leucodepletion of blood components in the UK. SACBC would like JPAC to consider how and to whom this information should be disseminated.

JPAC endorsed the paper and agreed that it should be circulated to the UK Quality Group, the UK Quality Managers and their Quality Monitoring sub-group. JJ

The possibility of producing a JPAC Position Statement was discussed and RC agreed to take this back to SACBC for consideration. RC

Phil Yates arrived at 13:16

ACTION

7.3 **Pathogen Inactivation of platelets - JPAC 13-22 Confidential**

JPAC noted that this paper was confidential.

RC went through this paper for JPAC, which was to review data on efficacy and safety of pathogen inactivated platelets in order that a draft specification and component codes can be approved and that platelets from validation studies can be issued for clinical use.

JPAC approved the draft specification, to include a storage time of up to 7 days of storage.

Actions:

- RC will update the paper with JPACs comments and send the amended version to CJS for recirculation to members.
- AB will feed back to SaBTO. AB
- The specification will be posted in the "Trial Section" on the JPAC website.

Post Meeting Note: JPAC 13-22 Amended was circulated to JPAC on 30 April 2013. Change Notification No 12 2013 Platelets in additive solution and plasma, leucocyte depleted, pathogen reduced (trial component) was issued on 27 June 2013

8. **JPAC Decision Making Framework – JPAC 13-23**

SM went through this latest version of the framework, produced following a telecon with SAC Chairs in January.

It was noted that the 3 tables taken from the NBS Risk Management procedure were out of date and therefore these need updating.

SM asked the SAC Chairs to trial the framework on a couple of recent items submitted to JPAC, one straightforward and one more complex. SAC Chairs

9. Draft report from the ISBT 128 Workshop held on 23 & 24 October 2012 – JPAC 13-24

9.1. SM went through the report for JPAC. It was felt that one of the strengths of the workshop was that quite a few "Users" took part. The report would now go to the next UKBTS Forum meeting.

Further work is now being undertaken on blood component labelling by a Steering Group and a Working Group.

Post Meeting Note: The report went to the UK Forum Meeting on 14 June.

9.2 **UK Blood Services blood component labelling survey – JPAC 13-35**

The Blood Component Labelling Working Group have produced a survey (JPAC 13-35) which will be circulated to hospitals in April.

JPAC endorsed the draft letter and the survey with one minor amendment -

ACTION

changing BTS to Blood Services in the text of the letter.

10. Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition

The hard copies of the new edition of the Red Book have been delivered to the 4 UK Blood Services.

All the UK Quality Managers had agreed a 3 month implementation date.

Post Meeting Note: A log of significant changes to the 8th Edition of the Guidelines for the Blood Transfusion Services in the UK, to be brought to the attention of the 4 UK Blood Services, was sent to the 4 UK Quality Managers on 4 April 2013.

11. UK BTS Forum

Feedback from the UK Forum meetings on held 13 December 2012 and 15 March 2013

There were no major issues to report to JPAC.

12. Annual Report for the UK Forum from UK BTS Quality and Regulatory Group - September 2012 – JPAC 13-25

JJ went through the annual report, which had been circulated to JPAC for information.

JJ told JPAC that Alan Slopecki's input to the Quality Managers Group had been huge and SM said that he had also contributed significantly to the work of JPAC for NHSBT. He will be very sadly missed.

13. SaBTO update

AB gave an update from the December 2012 meeting and issues currently under discussion.

- Prion filtration

SaBTO accepted the recommendations of the Prion Sub-Group regarding the PCapt prion reduction filter, the details of which should be published shortly.

Asahi Kasei Ltd informed the UK Blood Services Prion Working Group of their decision to cease development of the Asahi prion reduction filter at the present time.

- Hepatitis E

SaBTO received a report on transfusion related transmission of hepatitis E. A 12 month hepatitis E incidence study has commenced, led by PHE, with lookback to investigate transmissibility of HEV by blood transfusion and outcome of infection.

- 'Club 96'

A UK Blood Services working group continues to consider the use of blood

ACTION

donations from those born after 1.1.96 as a source of low vCJD risk blood for transfusion. SaBTO accepted the recommendation of the group to commence with IUTs and neonatal transfusion. The risk of transmission of other viruses including EBV, CMV and Adenoviruses currently not detected through routine screening is being assessed.
The working group will be undertaking a review of the MSBTO recommendation to only manufacture blood products for IUT, neonates and infants from second or subsequent donations following the universal use of NAT testing of all blood donors.

- MSM tissue donation

A draft report from SaBTO working group reviewing the criteria for the donation of tissues and cells by MSM will go to consultation imminently prior to formally reporting to SaBTO in June 2013.

- Platelet components

Following a review of the risk of vCJD transmission SaBTO has commenced a review of the recommendation to supply 80% of platelets from apheresis. SaBTO will oversee a simultaneous review of the cost effectiveness and clinical efficacy of Pathogen Inactivation of platelets.

- Two new SaBTO working groups have been established.

The Donor Organ Risk Assessment WG will produce guidance on the risks associated with specific diagnoses, the effect on specific organs for transplant and appropriate management of such scenarios.

The Cell Based Advanced Therapies WG will review the endogenous risks associated with Cellular Therapies particularly with respect to donor selection, consenting and testing, and make recommendations to SaBTO on how these can be optimised in order to support the development of Cellular Therapies in the UK whilst maximising donor and patient safety.

- West Nile virus and organ transplantation

A guidance document for the management of West Nile Virus in Solid Organ transplantation has been developed. This is currently undergoing formal consultation prior to final publication.

14. JPAC website transfusionguidelines.org.uk – JPAC 13-26

SM went through the paper and the draft terms of reference of the Steering Group, which had been submitted to JPAC for information.

15. Any Other Business

15.1 **The change to package Insert for Chloraprep® - JPAC 13-27**

SF had submitted this paper to make JPAC aware this change in the United States. JJ agreed to keep a watching brief for JPAC.

Post Meeting Note: JJ had been informed that the increase in drying time for the wand was not going to apply to the United Kingdom market and would not appear on the product insert.

ACTION

15.2 **Observers at JPAC meetings**

JPAC did not in principle disagree with having an occasional observer at the JPAC meetings.

15.3 **Dates of JPAC Meetings in 2014**

The following dates for JPAC meetings in 2014 were agreed.

- Thursday 27 March
- Thursday 17 July
- Thursday 13 November

15.4 **CoE Guide on Tissues and Cells**

SM informed JPAC that she had been made aware that the draft "Guide to the quality and safety of tissues and cells - 1st edition" was now out for consultation.

SM had asked PY and SACTCTP to comment on the guide for JPAC. It was noted that there had been a very short time scale for a response (4 days).

Post Meeting Note: Comments from the SACTCTP had been sent to VG to feedback through HTA.

Meeting closed at 15:08

16. Date & Venue for future JPAC meetings

2013

- Thursday 4 July - Association of Anaesthetists, London
- Thursday 14 November - Association of Anaesthetists, London

2014

- Thursday 27 March - Association of Anaesthetists, London
- Thursday 17 July - Association of Anaesthetists, London
- Thursday 13 November - Association of Anaesthetists, London