APPROVED 21/03/2013

Joint UKBTS/HPA Professional Advisory Committee

Minutes of the 53rd meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 8 November 2012

Meeting commenced at: 11:00

Present

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
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
Mr Nigel Goulding	**(NG)**	-	Medicines & Healthcare products Regulatory Agency
Dr Ines Ushiro-Lumb	**(IUL)**	-	Standing Advisory Committee on Transfusion Transmitted Infections *(Deputising for Dr Pat Hewitt)*
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Edwin Massey	**(EM)**	-	Standing Advisory Committee on Immunohaematology *(Deputising for Dr Nay Win)*
Dr Joanne Murdock	**(JM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Stephen Thomas	**(ST)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant

SM Welcomed Dr Ines Ushiro-Lumb, representing SACTTI and Dr Edwin Massey, representing SACIH, to this JPAC meeting. JPAC also congratulated Dr Stephen Field on his appointment to Medical Director of the Welsh Blood Service.

ACTION

1. Apologies

Dr Victoria Gauden	**(VG)**	-	Human Tissue Authority (HTA)
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
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 Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
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 28 June 2012 – JPAC 12-56

The minutes were accepted as a true record of the meeting.

ACTION

3. Matters arising not on the agenda (Review of actions list) JPAC 12-57

3.1 Recommendations for changes to acceptance criteria for UK whole blood and component donors with mild to moderate ischaemic heart disease – JPAC 11- 44 – item 3.2

SM informed JPAC that this may be superseded as this topic is on the list of proposed changes to the EU Directive - if this is accepted by the EU then this will become a new action.

3.2 JPAC Decision Making Framework – JPAC 11-48 – item 3.3

JPAC had a long discussion on the best way of taking this forward. It was agreed that it was important for JPAC to develop this framework to assure consistency and transparency of the decision making process.

SM informed JPAC that there is a European Up-Front Risk Assessment Tool (EUFRAT) model which was developed to provide quantitative transmission risk estimates of Emerging Infectious Diseases through blood transfusion. This is available on the Transfusion website.

Post Meeting Note: 09 November 2012 - CJS circulated the link to Modeling the transmission risk of emerging infectious diseases through blood transfusion, Welling Oei, Mart P. Janssen, et al, which is in the Early View section of the Transfusion website.

The following actions were agreed:

- SM would take this forward with the SAC Chairs and set up a small working group.
- CJS will organise a telecon for the first working group meeting
- LL will send will send CJS the SNBTS HiFi Framework (Health Impact and Finance Impact.
- SF will send CJS the Welsh risk assessment FMEA (Failure Mode and Effects Analysis)

Post Meeting Note: The Working Group has been set up consisting of SM, CJS and the SAC Chairs. The first meeting will take place on 23 January 2013. The SNBTS HiFi Framework and the Welsh FMEA have been received

3.3 Methylene Blue Plasma – current status – JPAC 12-08 – item 3.4

RC informed JPAC that AFSAPPS does not exist anymore and but she has now had a response from its replacement ANSM as well as Macopharma and Octapharma. No major concerns had been raised and ANSM thought that their data had been summarised correctly.

It was agreed that RC will send the revised Position Statement to SHOT and SM for approval and then it will be posted in the Document Library on the JPAC website.

SHOT have proposed that the analysis of data be presented as an original article, possibly in the British Journal of Haematology, and Transfusion Medicine are interested in publishing a review of the safety and efficacy of MB FFP.

Post Meeting Note: The JPAC Position Statement Methylene Blue-Treated Plasma was posted in the Document Library of the JPAC Website on 7 January 2013.

ACTION

3.4 Mobilised Granulocytes – JPAC 12-38 – item 4.5

This work is not included in the CoE guidance and it was agreed that SM will take this to the next Working Group on the Guide to the preparation, use and quality assurance of blood components (GTS) meeting in March 2013 for consideration of inclusion in the 18th Edition of the Guide. **SM**

3.5 Acupuncture consultation – item 4.6

SM informed JPAC that a response to our comments still awaited from the CHRE.

3.6 JPAC Position Statement on Methylene Blue-Treated Plasma – JPAC 12-44 item 6.4

See item 3.3 above.

3.7 Liquid Plasma for Emergency Use – JPAC 12-54 – item 6.5

MHRA had give us dispensation to use Liquid Plasma until 30th October 2012. This date has passed; therefore this item is now closed. It was noted that this product had not been required/issued.

4. Standing Advisory Committee on Transfusion Transmitted Infections

4.1 Babesia risk assessment v2 - JPAC 12-58

This risk assessment includes updated information about transfusion-transmitted Babesia in the United States.

JPAC endorsed the recommendation that no specific actions are required for the UK Blood Services.

It was agreed 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. ST commented that NHSBT had developed a 'Heat Map' which may be useful in this exercise.

ST to forward 'Heat Map' to CJS.

Post Meeting Note: ST has circulated the Horizon Scanning 2012 Heat Map v6 to CJS, SM, IUL and LW on 08-11-12.

IUL to discuss with SACTTI. **IUL**

4.2 Chikungunya Virus risk assessment v4 - JPAC 12-59

This risk assessment has been updated with the addition of many recent references/abstracts giving information about outbreaks of Chikungunya, clinical outcomes, laboratory testing, and modes of transmission.

Although Chikungunya infection continues to occur in many areas of the world, most are also malaria-endemic and donors are excluded for 6 months after return from the area. No new outbreaks in previously unaffected areas have been reported recently, so no new action is necessary at this time. Any extensive outbreak in a new area not subject to malaria-deferral guidelines should continue to be managed as before, with deferral of donors returning from such an area for 28 days.

It was noted that there is little information on areas affected by Chik V which do not

ACTION

have Malaria.

SI informed JPAC that the World Health Organisation (WHO) have a new blood regulators network set up and he will contact WHO, ask which groups are doing infection monitoring, and report back to JPAC. **SI**

JPAC endorsed the recommendation to continue with the current guidelines for Chikungunya infection outbreaks.

4.3 Leishmania risk assessment v2 – review only - JPAC 12-60

This risk assessment was reviewed by SACTTI in October 2012 and no changes were made.

JPAC endorsed the recommendation that no action is required by the UK Blood Services.

4.4 Lymphocytic Choriomeningitis Virus (LCMV) risk assessment v3 – JPAC 12-61

JPAC endorsed the risk assessment and recommendation to keep the matter under review. No specific action is warranted or feasible, taking into account current information.

4.5 Toxoplasmosis risk assessment v3 - JPAC 12-62

This risk assessment has been updated to include more information on pathogenesis and natural history of infection. It was noted that two UK Blood Services are planning seroprevalence studies.

JPAC endorsed the recommendation that no action is required by the UK Blood Services.

4.6 Novel Coronavirus (CoV) infection: Qatar/ Saudi Arabia 2012 - information for JPAC - JPAC 12-63

Novel Coronavirus (CoV) infection has been brought to the attention of JPAC for information only at this time.

4.7 Usutu Virus (USUV) - information for JPAC - JPAC 12-64

Usutu Virus (USUV) belongs to the Flaviviruses, genus Flavivirus, part of the Japanese encephalitis serocomplex and JPAC 12-64 has been submitted to JPAC for information only.

JPAC endorsed the recommendation that no action is required by the UK Blood Services at this time.

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

JPAC approved the publication of the one page summary sheet, page 2 of this paper, on the JPAC and HPA websites.

Post Meeting Note:

1. *This was discussed with PEH after the meeting, and she felt that the cover sheet should remain as submitted as this was information for JPAC, to explain why a previous decision by JPAC had not been followed though. To be discussed at the next meeting.* **PEH**

ACTION

2. This update version of the Position Statement was posted on the JPAC website on 27 November 2012.

5. Standing Advisory Committee on Care and Selection of Donors

5.1 Recommendation to change the Donor Selection Guidelines with regard to sickle cell trait and apheresis - JPAC 12-65

JPAC endorsed the recommendation to remove the restriction on sick cell trait donors from donating by apheresis and a change notification will be issued.

Post Meeting Note: The source files for Change Notification No. 27 2012 Sickle cell trait and Apheresis were available for training on the JPAC website on 8 January 2013 and the changes went live on 5 February 2013.

5.2 Clarification to the Donor Selection Guidelines for Chronic Kidney Disease - JPAC 12-67

SB informed JPAC that blood donation staff have had difficulty interpreting the guidelines with regard to chronic kidney disease and SACCSD would like to amend the guidance to clarify and simplify decision making at donor sessions.

JPAC endorsed this recommendation and a change notification will be issued.

Post Meeting Note: The source files for Change Notification No. 28 2012 Chronic Kidney Disease were available for training on the JPAC website on 8 January 2013 and the changes went live on 5 February 2013.

5.3 Proposed new entry for the Donor Selection Guidelines - Decompression illness - JPAC 12-68

Recreational and commercial diving is a growing industry and the SACCSD felt that guidance was needed to cover decompression illness.

JPAC endorsed the recommendation to add a new entry to the donor selection guidelines for Decompression Illness and a change notification will be issued.

Post Meeting Note: The source files for Change Notification No. 9 2012 Decompression Illness were available for training on the JPAC website on 8 January 2013 and the changes went live on 5 February 2013.

5.4 GDRI changes consequent on the changes to distribution of West Nile Virus (WNV) - JPAC 12-69

JPAC endorsed the recommendation that the JPAC Chair no longer needs to seek approval from the Medical Directors when issuing a change notification to update the Geographical Disease Risk Index (GDRI) following new outbreaks of WNV.

In future, once alerted by the ECDC, the Professional Director of JPAC and the Chairs of the SACs on Transfusion Transmitted Infection and Care and Selection of Donors (or their deputies) will review the evidence. They will then agree whether or not a change notification should be issued.

Post Meeting Note: Prof Marc Turner was not present at the meeting but has confirmed to CJS that he also approves this change in procedure for WNV updates in the GDRI.

ACTION

6. Standing Advisory Committee on Immuno-Haematology

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

The proposal for additional phenotyping had been previously discussed at the JPAC meeting in March 2012 (JPAC 12-10) and SACIH had been asked to provide further data for the risk assessment, which is included in JPAC 12-70.

JPAC endorsed the recommended proposal for additional phenotyping in JPAC 12-70 with the exception of the 3rd bullet point. New wording was suggested, as below, to provide clarity.

13.11.3 Additional phenotyping

- Red cell components should only be labeled with confirmed extended phenotypes
- A confirmed phenotype is one where the typing has been carried out and results concur
  - in duplicate on the current donation or
  - once on the current donation and the result is in agreement with historic data from previous donations or
  - ~~in duplicate on two donations from that donor~~
  - on two previous donations from that donor

Post Meeting Note: The above wording appears in the new edition of the Red Book.

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. **NW**

6.2 Red Cell Unit for Intra Uterine Transfusion and Exchange Transfusion with Positive Direct Antiglobulin Test – JPAC 12-71

JPAC endorsed the following recommendations:

1. In the unexpected event of a positive DAT detected while crossmatching blood for IUT/exchange transfusion, this issue should be discussed with the relevant clinicians (obstetrician/paediatricians). If time permits the index unit should be returned and a replacement unit issued. But for an urgent situation after discussion and agreement, the DAT pos unit can be used under concession.
2. Introducing testing of DAT screening for blood for IUT/Exchange would have no impact on clinical safety and will have additional burden on donation testing, and therefore it is unwarranted.

7. Standing Advisory Committee on Information Technology

7.1 Octaplas Product Labelling – JPAC 12-72

From September 2012 Octapharma, the manufacturers of the product Octaplas will be issuing the product with a new label. This paper points out potential issues.

Representation from SACIT and SACBC have reviewed the label and found a number of issues that make this label sub-optimal and cause difficulties for operational implementation.

ACTION

It was noted that this is not a JPAC responsibility as this is a medicinal product, but it may have implications for hospitals and Blood Services who supply hospitals with Octaplas.

JPAC did not object to the suggested changes set out in this paper being sent to Octapharma for discussion with the MHRA. It was agreed that the UK Quality Group should also be informed.

Post Meeting Note: LL has informed the Quality Managers.

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

NG went through the notes from the National Competent Authorities for Blood Meeting for JPAC.

There were a large number of presentations made at the meeting. These total 44MB and were too large to electronically circulate to JPAC. Copies of individual presentations, listed on page 6 of JPAC 12-73, are available from NG on request.

Potential Review of the EU Directives

NG thanked JPAC and the SAC Chairs for their contribution to the review. The Commission were grateful for all our suggestions.

As there was limited time the Commission only gave a summary of the suggestions received.

The proposed process is to collect views over the next 6 months, then assess changes.

It was noted by JPAC that there is still a window period to make some additions to the original comments submitted by the UK. This could include proposed changes to labelling. LL will formulate a proposal on labelling to put forward to NG for consideration.

Post Meeting Note: RC reviewed the EU Directive with regard to possible changes in labelling, which were discussed at the ISBT128 2 day Workshop last October, and sent a list of proposed changes to SM and LL. "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 further discussed at the Blood Consultative Committee meeting on 6 March and it was suggested that SM send NG a more detailed proposal. **SM**

Amongst the other items discussed were the draft Resolution of the CoE concerning risk behaviours for donor deferral, the advice from EC Legal Services that platelet rich plasma came within the scope of the Blood Directives and the review of the blood market being undertaken by the company, Creativ-Ceutical, on behalf of the EC.

9. SaBTO

9.1. Minutes of the SaBTO meeting held on 11 September 2012 – JPAC 12-74

ST went through the items from the last SaBTO meeting which were relevant to JPAC.

Item 4 (b) Methylene Blue (MB) treated fresh frozen plasma (FFP)

ACTION

SaBTO endorsed JPAC's view that no action was currently required, but that increased haemovigilance should be undertaken.

Item 4 (c) ACDP Position Statement and HPA Health Protection Report

The study of archived appendix samples from people born between 1941 and 1985 is now complete and two further studies on appendix samples are proposed.

Item 6: Relating to microbiological risk associated with stem cell therapy

Following discussions between SaBTO and a number of regulatory agencies, a working group will be set up to review the microbiological safety of Cell Based Advanced Therapies."

Item 7: Update on the MSM tissues & cells donor selection working group

This work is progressing. The Working Group is meeting again in late November, will update SaBTO at its next meeting in December and report its recommendations in early 2013.

Item 8.5.2: Commercial sex workers

SaBTO agreed that it could take no further action at this time. This item is now closed.

Next SaBTO Meeting

Next SaBTO meeting will take place on 10 December 2012. Main item for consideration is Prion filters

SaBTO meeting dates for 2013

Tuesday 5 March 2013
Monday 24 June 2013
Tuesday 25 June 2013 – Open meeting
Tuesday 17 September 2013
Tuesday 3 December 2013

The Open meeting due to take place in December 2012 has been postponed until the summer of 2013.

10. Guidelines for the Blood Transfusion Services in the United Kingdom

10.1. Update on the production of the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book) - 8th Edition – JPAC 12-75

Progress on this was noted.

11. JPAC website transfusionguidelines.org.uk

11.1 Redevelopment of the JPAC website – JPAC 12-76

Progress noted.

ACTION

12. UK BTS Forum

12.1 Feedback from the UK Forum meetings on held 3 July and 14 September 2012 – JPAC 12-77

SM updated the group on items of interest to JPAC from the last two UK Forum meetings. These were:

3 July 2012 (by teleconference)

- JPAC 2012/3 Workplan
- Website redevelopment
- Joint SACIT / SACBC ISBT 128 Workshop
- JPAC HEV risk assessment

14 September 2012, London

- Redevelopment of JPAC website
- Changes to the EU Blood Directives
- Systematic Reviews Initiative

13. ISBT 128 Workshop

13.1. Report from the ISBT 128 Workshop held on 23 & 24 October 2012 – JPAC 12-78

Report will come to next JPAC.

14. Annual Report for the UK Forum from UK BTS Quality and Regulatory Group - September 2012 – JPAC 12-79

As Joan Jones was unable to attend this meeting the annual report has been deferred to the next JPAC meeting in March 2013.

Post Meeting Note: This has been placed on the agenda for the meeting in March 2013.

15. TS043: Results of the public enquiry 17th Edition of the blood guide

15.1 Principles – JPAC 12-86

These were circulated for information.

15.2 Standards – JPAC 12-87

These were circulated for information.

16. Any Other Business

LW informed JPAC that Steve Thomas' secondment to SaBTO is coming to an end and asked CJS if she would circulate the Job Description to JPAC members. The secondment is for 18 months.

Action: LW will send CJS the job description.

Post Meeting Note: The SaBTO job description was circulated to JPAC.

ACTION

Grateful thanks were extended to Steve for his contribution to JPAC during his secondment.

IUL informed JPAC that Notify Library, managed by the Italian National Transplant Centre, has now gone live web address is http://www.notifylibrary.org

Meeting closed at 14:48

17. Date & Venue for future JPAC meetings

2013

- Thursday 21 March - Association of Anaesthetists, London
- Thursday 4 July - Association of Anaesthetists, London
- Thursday 14 November - Association of Anaesthetists, London