APPROVED 08/11/2012

Joint UKBTS/HPA Professional Advisory Committee

Minutes of the 52nd meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 28 June 2012

Meeting commenced at: 11:09

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)**	-	Acting 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 Patricia Hewitt	**(PEH)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Mr Alan Slopecki	**(AS)**	-	Representing the Quality Managers of the 4 UK Blood Services
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Stephen Thomas	**(ST)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
Dr Phil Yates	**(PY)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products

ACTION

1. APOLOGIES

Mr Ian Bateman	**(IB)**	-	Representing the Quality Managers of the 4 UK Blood Services
Dr Victoria Gauden	(**VG)**	-	Human Tissue Authority (HTA)
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
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)
Dr Joanne Murdock	**(JM)**	-	Medical Director, Northern Ireland Blood Transfusion Service

2. MINUTES OF THE LAST MEETING HELD ON 15 MARCH 2012 – JPAC 12-32

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

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 12-33

3.1 Review of high titre anti-A/B testing of donors within the UK Blood Services –

ACTION

JPAC 10-40 – item 3.1.

This item relates to the component portfolio and labelling and will be discussed later in the agenda. Closed

3.2 Recommendations for changes to acceptance criteria for UK whole blood and component donors with mild to moderate ischaemic heart disease – JPAC 11- 44 – item 3.5

SB has written to several cardiologists and received one response. The SACCSD plan is to produce a paper highlighting 5 areas with evidence for change which will be brought to JPAC. JPAC will then decide if this should go to the CoE or EU for discussion. **SB**

Phil Yates and Alan Slopecki arrived at 11:15

3.3 JPAC Decision Making Framework – JPAC 11-48 – item 3.9

SM

Carry over to next JPAC meeting.

3.4 Methylene Blue Plasma – current status – JPAC 12-08 – item 5.1

RC had requested further information from AFSAPPS (Agence Francaise de Securite Sanitaire des Produits de Sante) about the data on which their decision was made, but has received no reply as yet. She has had some communication with colleagues in France who are publishing a letter which clarifies some of the issues.

RC had commissioned further work on fibrinogen content of UK MBFFP and this information appears in the new JPAC Position Statement on Methylene Blue-Treated Plasma (see item 6.4). It was agreed that the position statement should be sent to colleagues in France to check that their data has been portrayed accurately. **RC**

At the last JPAC meeting it was agreed that we should recommend robust investigation of severe allergic reactions to FFP to determine the underlying cause. This recommendation is now in the new BCSH guidelines and the SHOT report.

4. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

4.1 Recommended changes to the Geographical Disease Risk Index (GDRI) for Iran, Iraq and Vietnam – JPAC 12-34

Following an assessment of risk SACCSD has re-written the entries for Iran and Iraq and revised the entry for Vietnam to include the main cities and airports. JPAC endorsed these changes.

Post Meeting Note: Change Notification No 20 2012 was issued on 20 October and the changes will be Live on the JPAC website on 31 October 2012.

4.2 Clarification to the Geographical Disease Risk Index for the USA – JPAC 12-35

JPAC endorsed the recommendation to remove Hawaii, Alaska and the US Virgin Islands (St Choix, St John and St Thomas in the Leeward Islands) from the West Nile Virus measure for the USA.

Post Meeting Note: Change Notification No 21 2012 was issued on 20 October and the changes will be Live on the JPAC website on 31 October 2012.

ACTION

4.3 Clarification to the Donor Selection Guidelines with regard to cupping/wet cupping – JPAC 12-36

It was noted that in the entry for "Complementary Therapy" on page 2, under "Additional Information", "and HBV DNA" should be added and the third paragraph should read "During the recovery phase of HBV infection levels of free HBsAg and HBV DNA may be too low to detect. Antibody to hepatitis B core antigen may be the only indicator of infectivity."

JPAC endorsed the recommendation to add this new index item, which will be linked to the Complementary Therapy topic, and the small change to the text of this topic regarding HBV DNA.

Post Meeting Note: Change Notification No 22 2012 was issued on 20 October and the changes will be Live on the JPAC website on 31 October 2012.

4.4 Clarification to the Donor Selection Guidelines with regard to Cardiovascular Disease – JPAC 12-37

The previous entry only referred to asymptomatic mitral valve prolapse. For clarity the topic would include information on incidental heart murmurs and valve abnormalities which have not required follow up.

JPAC endorsed the recommended entry with one minor amendment under Discretionary (d) which should say "a transfusion history" not "their transfusion history".

Post Meeting Note: Change Notification No 23 2012 was issued on 20 October and the changes will be Live on the JPAC website on 31 October 2012.

4.5 Mobilised Granulocytes – JPAC 12-38

Ian Franklin arrived at 11:30.

The Whole Blood and Component DSG does not state an appropriate interval between mobilised granulocyte donation and whole blood/component donation.

JPAC endorsed the recommendation to change the Frequency of Donation topic (c) Apheresis Mobilised Granulocytes with regard to inter-donation interval – *An apheresis granulocyte donor returning to whole blood donation should wait a minimum of eight weeks.*

This is not included in CoE guidance and it was agreed that SM will take this to the Working Group on the Guide to the preparation, use and quality assurance of blood components (GTS). **SM**

Post Meeting Note: Change Notification No 24 2012 was issued on 20 October and the changes will be Live on the JPAC website on 31 October 2012.

4.6 Acupuncture consultation

SB informed JPAC that we have been made aware by the British Acupuncture Council that the Council for Healthcare Regulatory Excellence (CHRE) are conducting a consultation on proposals for voluntary accreditation of associations in the healthcare field and this will include acupuncturists. This will accredit the association and not the person giving the treatment.

SB and SM have drafted a response to the consultation on behalf of JPAC.

ACTION

SM and SB will take this forward. **SM & SB**

IF commented that there is little data on how many donors we lose due to acupuncture deferral and consideration should be given to performing a survey.

5. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

5.1 The estimated risk of HBV, HCV and HIV potentially infectious donations entering the UK blood supply due to the window period of tests in use, 2008 – 2010 – JPAC 12-39

PEH informed JPAC that HTLV is no longer included in these estimates and the following explanation appears in the summary:

Despite anti-HTLV testing of blood donations in the UK, the risk of a potentially infectious donation entering the blood supply due to a window period donation not detected through testing has not been estimated. This is because of i. the uncertainty about the presence and/or duration of an infectious window period for HTLV and ii. the relevance of the calculation, given that widespread leucodepletion of all components is likely to significantly reduce onwards transmission to patients.

PEH confirmed that only the first page Summary and the Summary Table are published on the JPAC website.

5.2 Hepatitis E (HEV) risk assessment v1 – JPAC 12-40

PEH went through this paper for JPAC. Work on the Hepatitis E (HEV) risk assessment has been a priority for SACTTI.

JPAC noted that this is an area for concern and that HEV may represent a significant threat to transfusion recipients, especially the immunosuppressed. JPAC supports efforts to obtain further epidemiological information in relation to prevalence and incidence of infection in the donor population, risk factors for acquisition of infection, and evidence of chronic infection in immunosuppressed recipients.

PEH informed JPAC that a proposal for work to answer the questions posed in the summary sheet has been submitted jointly by the HPA Blood-Borne Virus Unit and NHSBT to the Research Ethics Committee and this has just received ethical approval.

It was agreed that JPAC would keep the situation under review and this paper should be submitted to the UK BTS Forum meeting on 3 July.

Post Meeting Note: This paper was submitted to the UK BTS Forum meeting on 3 July 2012.

SM asked if the virus is affected by pathogen inactivation systems. RC will investigate.

Post Meeting Note: Mirasol results in a > 2 log reduction in hepatitis E. Cerus have not studied Hepatitis E, however their systems results in 2 logs of inactivation feline calicivirus which is closely related, and would therefore anticipate a similar degree of inactivation of hepatitis E.

ACTION

6. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

6.1 Interruption of platelet agitation - JPAC 12-41

JPAC endorsed the change of wording in the 8th Edition of the Red Book in the section: Specifications for Blood Components a) pooled platelets and b) apheresis platelets, as follows:

"Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided the interruptions are for no longer than ~~a single episode~~ **a total** of 24 hours".

6.2 The design of future UKBTS full face blood component labels – JPAC 12-42

SM, SACIT and SACBC are planning a joint workshop on labelling and portfolio issues which is due to take place in Leeds on 23rd and 24th October 2012.

6.3 JPAC Position Statement on Granulocyte Therapy – JPAC 12-43

This position statement has been reviewed by members of SACBC and there were only a few minor changes.

It was noted that on page 5 under "Granulocytes derived from whole blood", second paragraph, England and Wales have had a significant increase in requests for the buffy coat granulocyte component over the last 5 years. SM asked RC to find out whether Scotland and Northern Ireland have had a similar increase in requests.

SM asked RC to remove the highlighted paragraph on page 7 and the highlighted reference to England and North Wales in the Summary on page 8.

JPAC approved the updated position statement with these amendments.

Action: RC will revise the position statement and send to SM.

Post Meeting Note: The JPAC Position Statement on Granulocyte Therapy has been revised and posted in the Document Library on the JPAC website.

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

RC presented the proposed position statement on Methylene Blue Plasma in which the data contained in the previous paper has been updated (JPAC 12-08).

It was agreed that the paper should be forwarded to the manufacturers of pathogen inactivation plasma systems referred to in the paper for accuracy and also to EFS and AFSAPPS to confirm that what we have said about the French data is accurate and correct. **RC**

A few minor amendments were agreed. The intention is to publish in a peer review journal and on the JPAC website. **RC**

6.5 Liquid Plasma for Emergency Use – JPAC 12-54

This paper had been circulated to JPAC prior to the meeting for comment and SM went through the comments which had been received.

ACTION

After considerable discussion the specification was approved with the proviso that this component would only be produced and issued for use in exceptional circumstances as part of contingency measures as outlined in the paper.

- SM will communicate this to NHSBT. **SM**
- SM will inform the MHRA about this new product. **SM**
- SM will liaise with Darren Elvidge about including the specification in a non-routine product area of the website. **SM**

Post Meeting Note: Updated paper JPAC 12-54 Amended – Liquid plasma for contingency for the treatment of diarrhoea-positive haemolytic uraemic syndrome was circulated to JPAC on 29-06-12.

7. STANDING ADVISORY COMMITTEE ON IMMUNO-HAEMATOLOGY

7.1 Additional testing in the Guidelines for the Blood Transfusion Services in the United Kingdom, Chapter 13 (Donation Testing), Section 13.11.2 Testing and issue of high titre anti-A/anti-B: red cells need further clarification – 12-45

JPAC endorsed recommended wording for the 8th Edition of the Red Book:

- Each blood establishment should have a testing and issuing policy to avoid the use of high-titre anti-A and/or anti-B in instances where a significant adverse clinical reaction is likely. The policy should cover the following components:
  - whole blood and plasma reduced red Cells (excluding red cells in additive solution)
  - fresh frozen plasma
  - apheresis platelet donations
  - pooled platelets containing plasma from a single 'high-titre' group O donor
  - blood/components for neonatal use and infants under one year

Post Meeting Note: These changes have been incorporated into Chapter 13 of the 8th Edition of the Red Book.

7.2 Proposed wording for the Guidelines for the Blood Transfusion Services in the United Kingdom, Chapter 13 (Donation Testing), new section 13.11.5. HbS Screening – JPAC 12-46

SF confirmed that Wales do not do any HbS testing.

7.2.1 Section 13.11.5 - JPAC approved the new wording regarding the new section 13.11.5 HbS testing which will appear in the 8th edition of the Red Book.

7.2.2 Section 13.11.3 - This paper proposed a significant change in the guidelines for provision of phenotype red cells. NW is still awaiting further data for risk assessment. The data on possible donor misidentification will also be included in this paper which will be submitted to the JPAC EWG in September. **NW**

8. SaBTO update JPAC 12-47

Stephen Thomas went through the report for JPAC.

The SaBTO meeting scheduled for 29 May was cancelled and SaBTO members had been provided with a briefing pack on current work. Extracts of the documents were provided for JPAC in JPAC 12-47 which included information on:

ACTION

- Tissues and cells donor selection working group
- Compliance with blood donor deferral criteria
- Advanced therapy medicinal products (ATMPs)
- Recruitment of new SaBTO members
- Letter re use of imported FFP for those born on/after 1st January 1996, and adult patients with TTP
- New SaBTO website
- SaBTO Annual Report 2011/12
- Minutes and papers of the SaBTO meeting on 9 March 2012

The next SaBTO meeting is due to take place on 11 September.

ST also updated JPAC on the work of the Club 96 UK Forum Working Group, which is working on optimal use of blood donated by donors born after 1st January 1996. JPAC will be asked to look at some aspects arising out of this work such as clarification of and flexibility of donor criteria and labelling issues.

It was agreed that items should be added to the JPAC Workplan reflecting potential work.

Post Meeting Note: This work has been added to the JPAC workplan.

9. COE – RISK BEHAVIOURS HAVING AN IMPACT ON DONOR MANAGEMENT – JPAC 12-48

9.1 NG fed back from the EU Blood Competent Authorities meeting on 20 April 2012. The general response from the Member States is that a risk-based approach should be adopted.

SM had received an updated version of the draft CD-P-TS Resolution on Sexual Behaviours in Blood Donors and this had been circulated to JPAC for information on 26 June 2012.

10. JPAC Workplans

10.1 JPAC Workplan 2011/12 – Final Outcomes (v3 19-06-12) – JPAC 12-49

SM congratulated all the SAC Chairs on the work carried out by their committees last year.

10.2 Draft JPAC Workplan 2012/13 (v4 21-06-12) – JPAC 12-50

The draft workplan had been drawn up following the SAC annual review meetings and has been submitted to the UK BTS Forum meeting on 3 July to add any actions from the UK BTS Forum and approval.

It was agreed that two further items should be added to the workplan (1) Club 96 Working Group and (2) EU Medicine Devices Directive and the updated workplan sent to the UKBTS Forum.

Post Meeting Note: Draft JPAC Workplan 2012/13 (v5 24-06-12) was circulated to the UKBTS Forum on 29 June 2012 for discussion at their meeting on 3 July.

ACTION

PEH left the meeting at 14:13

11. JPAC AND JPAC SACS TERMS OF REFERENCE – JPAC 12-51

11.1 The JPAC and JPAC SACs Terms of References had been reviewed at the SAC annual review meetings in which took place in May/June 2012.

There was only one small change and this was to the ToR for the SAC on Tissues and Cellular Therapy Products, last bullet point, to replace SAC on Blood Components with SAC on Information Technology.

JPAC endorsed the revised Terms of Reference.

12. JPAC WEBSITE TRANSFUSIONGUIDELINES.ORG.UK

12.1 Redevelopment of the JPAC website

SM updated JPAC on the redevelopment of the website. The contacted suppliers quote for a new website was too expensive. On JPAC's behalf LL has approached an NHS supplier in Scotland who has provided services for the SNBTS. They have been sent the JPAC Stakeholder Requirement Document. LL had agreed to progress this in the first instance and then hand over to Darren Elvidge.

SM informed JPAC that she is meeting with the suppliers in July, along with Darren Elvidge, to take this forward.

13. ANY OTHER BUSINESS

13.1 EU Commission Medical Device Directives Review

Alan Slopecki informed JPAC that the Medical Devices Directive are being rewritten and will be out for consultation later in the year.

The most significant potential change is that we will no longer be able to use the in house exemption to avoid CE marking class D products, these are essentially any test kits used for blood grouping or microbiology testing of donations of blood, tissues, organs and stem cells.

NHSBT are submitting a paper to their Executive to highlight the potential risks.

Action: As this could have consequences for the Microbiology, H&I and Immuno-haematology sections of the Red Book, SM asked AS to send this paper to NW and PEH with an explanatory note as PEH had already left the meeting and asked CJS to add this to the JPAC workplan.

Post Meeting Note: EU Commission Medical Device Directives Review - the potential impact on NHSBT (email from AS) was circulated to JPAC on 2 July 2012 and this item has been added to the JPAC workplan.

Meeting closed at 14:25

14. DATE & VENUE FOR FUTURE JPAC MEETINGS

2012

- Thursday 8 November - Association of Anaesthetists, London

2013

- Thursday 21 March - Association of Anaesthetists, London

ACTION

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