APPROVED 15/03/2012

Joint UKBTS/HPA Professional Advisory Committee

Minutes of the 50th meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 10th November 2011

Meeting commenced at: 11:03

PRESENT

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Mr Ian Bateman	**(IB)**	-	Representing the Quality Managers of the 4 UK Blood Services
Dr Rebecca Cardigan	**(RC)**	-	Standing Advisory Committee on Blood Components
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
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Lionel Mohabir	**(LM)**	-	Standing Advisory Committee on Immunohaematology **(SACIH section only)**
Dr Joanne Murdock	**(JM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Dr Stephen Thomas	**(ST)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
Prof Marc Turner	**(MT)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant
Dr Phil Yates	**(PY)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products

SM welcomed Marc Turner and Victoria Gauden to their first JPAC meeting and also Lionel Mohabir who is representing Nay Win for the SACIH section only.

SM also informed JPAC that, although Derek Norfolk is retiring from NHSBT at the end of the year, he will be continuing with his SACCTM work for a further 6 months to complete work on the next edition of the Handbook of Transfusion Medicine.

ACTION

1. APOLOGIES

Dr Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Prof James Neuberger	**(JN)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Health Protection Agency (HPA)

ACTION

2. MINUTES OF THE LAST MEETING HELD ON 30 JUNE 2011 – JPAC 11-52

The minutes were approved as a true record of the meeting with the addition of an action to item 4.10 to issue a Change Notification regarding the starting date for donor deferral for West Nile Virus in 2012.

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 11-53

3.1 Review of high titre anti-A/B testing of donors within the UK Blood Services – JPAC 10-40 – item 3.1.

The trial at the Welsh Blood Service is now complete - see item 4.1.

The question of whether the current wording of the label as Neg:HT, to indicate negative for high titre was the best way of providing information for hospitals, was discussed at a meeting on 18 April between SM, LL, Bruce Cuthbertson and Chris Prowse.

SM will discuss this with LL and RC as part of taking the Component Portfolio forward. **LL, RC and SM**

3.2 Recommendations on Donor Height and Weight – JPAC 11-10 – item 3.6

SB informed JPAC that a Change Notification is now in draft form and will be ready to send to the JPAC office at the beginning of December to allow the Services 1 month's notice for implementation at the beginning of January 2012. It was noted that the Change Notification will not have an implementation date but will say "To be determined by each Service".

Post Meeting Note: Change Notification No 22 2011 - Donor Weight was issued on 9 December 2011. Source files will be available for training from 16 December and the change will be live on the JPAC website on Tuesday 24 January 2012.

3.3 Revised Chapter 7 of the Red Book – JPAC 11-14 – item 3.8

The action was for Chris Prowse to seek permission from Blackwells to reproduce "Figure 1" which appeared in Transfusion Medicine 19, 329-339. Permission has been granted by Mr Mark Nightingale (one of the authors of the original paper) for an updated version of this algorithm to appear in the relevant chapter.

3.4 Blood Components – Proposed model for SNOMED-CT – JPAC 11-26 – item 3.11

The finalised paper will be taken to SNOMED UK to become part of SNOMED-CT technology and then international SNOMED and international ISBT.

LL will keep JPAC updated on progress. **LL**

3.5 West Nile Virus precautions for UK blood donors – starting date for donor deferral – JPAC 11-30 – item 4.10

ACTION

Action: Issue a Change Notification changing the "typical WNV season" date for affected areas to "from 1 May to 30 November" from 2012 onwards; not withstanding testing might be introduced. **SB**

3.6 Labelling of blood components – item 6.2

SACBC had raised a question regarding the use of the wording "Risk of adverse reaction/infection, including vCJD". SM had advised that there had been previous discussions on this matter and that vCJD should not be mentioned on the label of imported components. RC informed JPAC that the appropriate specifications in Chapter 8 of the next edition of the Red Book have been redrafted.

3.7 Prion filters – item 6.3

There are two General Information papers regarding prion filtration on the JPAC website:

- UKBTS General Information 06 – Evaluation of Efficacy of Prion Removal Filters – which is currently being updated by SACBC **RC**
- UKBTS General Information 07 – Validation of Blood Component Quality Following Prion Removal Procedures for Red Cell Components – which is currently being updated by the Prion Working Group **MT**

3.8 Recommendations for changes to acceptance criteria for UK whole blood and component donors with mild to moderate ischaemic heart disease – JPAC 11- 44 – item 7.1

SB will provide further information on definitions of severity of heart disease to the JPAC meeting on 28 June 2012. **SB**

3.9 JPAC Decision Making Framework – JPAC 11-48 – item 9.

After discussion at the UK BTS Forum in September it was agreed that SM would produce a paper for the Forum. **SM**

4. STANDING ADVISORY COMMITTEE ON IMMUNO-HAEMATOLOGY

4.1 Review of high titre anti-A/B testing of donors within the UK Blood Services – JPAC 10-40 – item 3.1.

SM gave a brief history of this paper for the Group.

This was brought to the attention of JPAC following the SHOT report in 2008, when 4 cases of acute haemolysis following platelet transfusion were reported.

SACIH have updated the previous paper, JPAC 10-40, to include an additional review of SHOT reports 1997 to 2010 and the findings of the Welsh Blood Service (WBS) study on comparative testing for high titre anti-A/B. Lionel Mohabir summarised the paper for JPAC.

The WBS study showed a poor correlation between anti-A/B IgM and IgG titres, but the outcome was that an anti-IgG screening titre of 1024 would identify the highest 5% of the donor population. It was agreed that introduction

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of testing for anti-IgG would have the potential to further reduce the incidence of acute haemolytic transfusion reaction, but would not be without operational difficulty, and therefore further assessment of risk versus benefit was warranted.

With regard to risk assessment, the review of recent SHOT reports showed that acute haemolytic reactions due to out of group platelet transfusion are extremely rare and no cases have been reported since 2008.

JPAC approved the SACIH recommendations to:

1) continue the current screening programme for anti-IgM only
2) continue to monitor adverse reactions through SHOT and
3) any suspected incident of acute haemolytic transfusion reaction due to platelet transfusion should be referred to the Blood Services for thorough investigation and reported to SACIH.

SM will report back to SHOT on the results of this review and recommendations. **Action**: SM **SM**

It was noted that there was an error on the Summary Sheet. The first bullet point in the "Brief summary" should say "platelet component" not "platelet concentrate". CJS will inform NW.

Post Meeting Note: JPAC 11-54 Amended circulated to JPAC on 21-12-11.

4.2 Working Party on DNA Reference Materials for Immunohaematology

This Working Party has been disbanded. NW will submit a short paper to the next JPAC meeting to clarify the arrangements regarding the work of the Working Party. **NW**

5. STANDING ADVISORY COMMITTEE ON TISSUE AND CELLULAR THERAPY PRODUCTS

5.1 Porphyria and tissue or cell donors – JPAC 11-55

JPAC endorsed the 3 new recommended guidelines (Living Tissue DSG, Deceased Tissue DSG and Bone Marrow and Cord Blood DSG) for porphyria and a Change Notification will be issued.

Post Meeting Note: Change Notification No 20 2011 Porphyria was issued on 1 December 2011.

5.2 Risk assessment for immunosuppression and corneal donation – JPAC 11-56

PY informed JPAC that this risk assessment is only for corneal donors.

JPAC endorsed the recommendation with two minor amendments. 1) the paper should refer to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 rather than the EC Directive and 2) it should include a list of any experts who had seen/contributed to the paper.
A Change Notification will be issued and this paper will be posted on the JPAC

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website as a supporting paper.

Post Meeting Note: Change Notification No 21 2011 Immunosuppression was issued on 1 December 2011. JPAC 11-56 was also posted in the Document Library of the JPAC website as a supporting paper.

6. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

6.1 Storage temperature (when frozen) of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP – JPAC 11-57

RC went through this paper for JPAC. SACBC had considered the evidence to support changing the temperature of storage of frozen plasma components from ≤ -30°C to ≤ -25°C in order to 1) bring the Red Book in line with CoE Guidelines and 2) make plasma storage more efficient (reduced running costs and purchase costs of lower specification freezers etc.)

It was stated on the summary sheet that SACBC had recommended that a Change Notification is not issued, but that the change should be incorporated into changes to Chapter 8 of the next edition of the Red Book. RC informed JPAC that since the paper had been submitted to this meeting SACBC have requested that a Change Notification should be issued.

JPAC endorsed the recommendation that the temperature of storage of all frozen plasma components be changed from ≤-30°C to ≤-25°C in line with CoE Guidelines. The shelf-life should remain 24 months. A Change Notification will be issued and the change will be incorporated in Chapter 8 of the next edition of the Red Book.

Post Meeting Note: Change Notification No 1 2012 – Storage temperature (when frozen) of fresh-frozen plasma (FFP), cryoprecipitate, cryoprecipitate-depleted plasma and methylene blue (MB)-treated FFP and cryoprecipitate was issued on 15 February 2012 and all changes have been made in the relevant areas on the website transfusionguidelines.org.uk

6.2 Thawing temperature of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP – JPAC 11-58

RC went through this paper for JPAC.

Equipment used in hospitals to thaw plasma components cannot meet the current UK recommendation of thawing at 37°C. This has been raised as a non-compliance when hospitals have been inspected by the MHRA since the capability of current equipment is to thaw between 33 and 37°C.

JPAC endorsed the recommendation that the thawing temperature of all frozen plasma components be changed from 37°C to 33-37°C and a Change Notification will be issued. It was noted that this information needs to be disseminated to hospital blood banks. It was therefore agreed that when the Change Notification is issued to the Medical Directors a note will be added requesting that they send the information on to hospitals within their country.

Post Meeting Note: Change Notification No 2 2012 – Thawing temperature of fresh-frozen plasma (FFP), cryoprecipitate, cryoprecipitate-depleted plasma and methylene blue (MB)-treated FFP and cryoprecipitate was issued on 15

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February 2012 and all changes have been made in the relevant areas on the website transfusionguidelines.org.uk. Medical Directors have been sent an email asking them to disseminate this information to hospitals within their country.

6.3 Shelf-life of frozen plasma components following thawing – JPAC 11-59

SACBC have been asked to consider whether the shelf-life of FFP following thawing can be extended from 24 hours to 5 days.

After considerable discussion JPAC agreed to not change the post thaw shelf-life of FFP from the current 24 hours.

Points discussed included:

- The laboratory data showing that coagulation factors declined during storage and therefore there is a possibility that efficacy would also decline.
- There are no clinical studies evaluating the use of FFP thawed and stored for 5 days.
- Any extension of post-thaw shelf-life could not be considered for cryoprecipitate, MB treated FFP or FFP for Neonates for varying reasons.
- There may be a new recommendation from SaBTO in 2012 for the type of FFP to be used in the UK.

It was felt there was not a strong clinical drive to extend the shelf-life.

7. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

7.1 Clarifications to DSG entries for Cardiovascular Disease, Surgery and Chronic Fatigue Syndrome including Accept – JPAC 11-60

JPAC approved these clarifications, but with regard to Chronic Fatigue Syndrome (CFS) JPAC requested a separate entry for XMRV which was not linked to CFS and also stating that XMRV is not associated with human disease. The new entry for XMRV would appear in all 5 DSGs.

Post Meeting Note: Change Notifications Nos 23 to 25 were issued on 9 December 2011. Source files will be available for training from 16 December and the changes will be live on the JPAC website on Tuesday 24 January 2012.

7.2 Entry in DSG to allow requalification of successfully treated patients who have had HCV – JPAC 11-61

JPAC approved the recommendation for people who have been successfully treated for HCV. Change Notification will be issued to cover all 5 DSGs.

Post Meeting Note: Change Notifications Nos 26 (WB DSG) and 27 (Tissues DSGs) were issued on 9 December 2011. Source files will be available for training from 16 December and the changes will be live on the JPAC website on Tuesday 24 January 2012.

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8. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

8.1 Xenotrophic murine leukaemia related virus (XMRV) and other murine retroviruses risk assessment version 4 – JPAC 11-62

Risk assessment has been updated to include 2011 new data and there is a significant amount of new information in the added references. The risk assessment will be reviewed again in 2 years time unless further information arises.

JPAC approved the risk assessment with a couple of amendments.

Post Meeting Note: This paper has been updated, renamed JPAC 11-62 Amended, and circulated to JPAC on 04-01-2012.

8.2 The estimated risk of HBV and HCV window period infections in surgical bone donors being missed by testing, England 2005 – 2010 – JPAC 11-63

PEH reiterated that the JPAC website does not publish these figures, but provides a link to the HPA website.

It was noted that this is NHSBT's bone donor data.

JPAC endorsed the paper with some amendments. **PEH**

8.3 The estimated risk of HBV, HCV, HIV and HTLV (type 1) potentially infectious donations entering the UK blood supply due to the window period of tests in use, 2008 – 2010 – JPAC 11-64

PEH went through this paper for the Group.

The summary paper looks at the most recent years 2008 to 2010. Additional information presented for JPAC gives the summary data for 2005-2010.

PEH was asked to ask the Epidemiology Steering Group whether we should be including HTLV risk, given the doubts about the relevance of any window period to the risk of an infectious donation. **PEH**

8.4 West Nile Virus (WNV) precautions for UK blood donors – JPAC 11-65

NG updated JPAC on the current situation regarding West Nile Virus (WNV).

The EU Directive 2004/33/EC and the Blood Safety & Quality Regulations 2005 require deferral of prospective donors for 28 days after return from an area of ongoing transmission of WNV to humans. The legislation does not provide for WNV-NAT testing of donations (or pathogen inactivation) as an alternative to deferral. Following a submission by JPAC to MHRA, MHRA had contacted the European Commission about a potential amendment to the Directive to permit WNV-NAT testing as an alternative to deferral. This would require the EC to adopt a Directive amending Directive 2004/33/EC, which could be possible as an emergency measure (e.g. as happened in 2009 with the relaxation of two donor acceptance criteria during a flu pandemic). NG explained that if the potential level of WNV donor deferrals in 2012 were assessed as posing a threat of blood / component shortages in the UK, a

ACTION

proposal could be made to the MHRA Executive Board that MHRA would not enforce the provision that donor deferral was the only response and by extension WNV-NAT testing could be used as an alternative. This would require Ministerial agreement. A similar approach was taken during the pandemic flu outbreak in the summer of 2009 in respect of certain donor acceptance criteria - although in the event it was not necessary.

LW reported that NHSBT had assessed the risk of deferral to supply in 2012 as unacceptable, particularly in the context of a requirement to build stock for the Olympics. A paper would be going to the November meeting of NHSBT's Board recommending that testing be implemented from 1st May 2012, as it would be impractical to introduce this part way through the mosquito season. This paper would assume that a solution to the regulatory issues would be found.

MT reported that SNBTS would also like to have the freedom to test donors. JPAC supported the approach being taken.

Post Meeting Note: The situation regarding West Nile Virus was discussed at the UK BTS Forum on 16 December. SM appraised the UKF of NG's comments above. There is to be a meeting in Brussels on 18 January to update the EU WNV preparedness plan.

8.5 Human Herpesvirus-8 risk assessment, version 3: supplementary information – JPAC 11-66

JPAC noted the information in JPAC 11-66 and reaffirmed the decision to keep a watching brief.

9. UK BTS FORUM: FEEDBACK – JPAC 11-67

9.1 West Nile Virus Issues

The UK BTS Forum agreed that the issue of WNV spreading in Europe was a considerable potential problem and asked SM to take forward further discussion with the MHRA about the use of testing as an alternative to donor deferral.

9.2 Recommendations on Donor Height and Weight

There was considerable discussion about this paper with the result that UK BTS Forum acknowledged that this should be accepted as a donor safety measure despite potential donor losses, and approved the recommendation to defer females under 20 years old with an estimated blood volume of less than 3.5 litres.

9.3 JPAC Decision Making Framework

LW clarified that her concern about the draft framework was that there would need to be a decision as to whether a cost effectiveness analysis should be included or not. This was not currently a formal part of JPAC 's decision making. SM agreed to produce a paper for the UK BTS Forum.

9.4 Better Blood Transfusion – Toolkit

ACTION

UK BTS Forum approved the request for JPAC to become the formal custodian of the BBT Toolkit.

9.5

ISBT 128 Project Manager

A final draft of the report should be ready for submission to the next UK BTS Forum meeting on 16 December 2011.

Post Meeting Note: Still awaiting report.

10. SaBTO update – JPAC 11-68

10.1 Review of blood donor selection

The situation regarding deferral of men who have had sex with men and tissue donation was discussed at length. It was noted by JPAC that as there isn't any data available for tissues it would be difficult for SACTTI to produce a risk assessment.

It was agreed that SACTTI and SACTCTP would produce a joint paper discussing the application of the change to the MSM rules to tissue and stem cell donation for the JPAC meeting in March. **PEH and PY**

10.2 Cytomegalovirus (CMV) transmission by blood transfusion

It was agreed that the JPAC Position Statement on CMV should be removed from the JPAC website and replaced with an explanation as to why the statement has been removed and a link to the SaBTO website.

Post Meeting Note: The JPAC Position Statement on CMV was removed from the website and replaced with an explanation and a link to the relevant page on the SaBTO website.

10.3 vCJD

ST informed JPAC that the meeting of the TSE risk assessment subgroup of the Advisory Committee on Dangerous Pathogens, due to take place on 10th November, had been postponed.

11. JPAC WEBSITE TRANSFUSIONGUIDELINES.ORG.UK

11.1 Development of the JPAC website v1 – JPAC 11-69

SM went through this paper for the group.

Post Meeting Note: This paper was submitted to the UK BTS Forum on 16 December where it was approved.

12. ANY OTHER BUSINESS

12.1 Reports of allergic reactions to methylene blue-treated FFP (MBFFP) from France – JPAC 11-70

ACTION

SACBC to produce a paper for JPAC in March.

MT left the meeting – 15:19.

13. DATE & VENUE FOR FUTURE JPAC MEETINGS

2012

- Thursday 15 March - Association of Anaesthetists, London **(New date)**
- Thursday 28 June - Association of Anaesthetists, London
- Thursday 8 November - Association of Anaesthetists, London

Meeting closed at 15:21