APPROVED 10/11/2011

Joint UKBTS/HPA Professional Advisory Committee

Minutes of the 49th meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 30th June 2011

Meeting commenced at: 11:02

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
Prof Ian Franklin	**(IMF)**	-	National Medical Director, Irish Blood Transfusion Service **(Chair)**
Mr Nigel Goulding	**(NG)**	-	Medicines & Healthcare products Regulatory Agency
Dr Patricia Hewitt	**(PEH)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
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
Dr Phil Yates	**(PY)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products

Due to illness SM could not attend this meeting. Prof Ian Franklin agreed to act as Chair in her absence.

ACTION

1. APOLOGIES

Dr Rebecca Cardigan	**(RC)**	-	Standing Advisory Committee on Blood Components
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
Dr Christiane Niederlaender	**(CN)**	-	Human Tissue Authority (HTA)
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
Prof Maria Zambon	**(MZ)**	-	Director, Centre for Infections, Health Protection Agency (HPA)
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC

ACTION

2. MINUTES OF THE LAST MEETING HELD ON 10 MARCH 2010 – JPAC 11-28

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

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 11-29

3.1 Review of high titre anti-A/B testing of donors within the National Blood Service (NBS) INF/MED/MA/004/02 – JPAC 10-40 - item 3.4

As SM, NW and LL were not able to attend this meeting the following two actions will be carried over to the next JPAC meeting in November.

The trial at the Welsh Blood Service is now under way and NW will feed back the results when available. **NW**

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 , will be discussed at a meeting on 18 April between SM, LL, BC and CP. **SM, CP & LL**

3.2 Reinstatement of 'non-specific' reactive tissue donors v1 – JPAC 10-65 – item 3.3

Prior to his retirement from the SAC on Tissues Roger Eglin had requested Su Brailsford, of the NHSBT/HPA Epidemiology Unit, to add residual risk values for HBV, HCV, HIV and HTLV for tissue donors to their work list.

PY informed JPAC that it is not possible to provide this information as the numbers of infected donors are too small to put into the model.

PEH informed JPAC that NHSBT Tissues has been having separate discussions with the Epidemiology Unit, as surgeons using bone would like to have some guidance regarding risk. There will therefore be further discussions between the Epidemiology group and NHSBT Tissue Services about a general statement about risk, similar to the information leaflets for blood transfusion recipients.

3.3 Dengue Virus risk assessment – JPAC 10-67 – item 3.4

This action was discussed under item 9.

3.4 Xenotrophic Murine leukaemia Related Virus (XMRV) risk assessment update v2 – JPAC 10- 68 – item 3.5

At the previous meeting LW had informed JPAC that Organ Donation and Transplant had followed up 20 recipients from donors with a history of CFS for 3 years and none have symptoms of CFS/ME. This work had been written up as an urgent letter to the Lancet.

LW asked CJS to approach Prof James Neuberger directly for the final version of this paper for circulation to JPAC.

Post Meeting Note: "Safety of solid-organ transplantation from donors with Chronic Fatigue Syndrome" which appeared in Transplantation was circulated to JPAC on 1st July 2011.

ACTION

3.5 Quality Control standards for monitoring Fresh Frozen Plasma – JPAC 10-73 – item 3.7

The MHRA had taken this paper to the EU Competent Authorities meeting and asked for feedback. NG reported that responses were negligible from other MSs concerning their national positions on the monitoring of Factor VIII levels in FFP and in consequence the matter was not discussed at the NCA's meeting.

NG further reported that the EC and CoE/EDQM have agreed to set up a joint working group to elaborate common European standards and the good practice guidelines for blood establishments as required by Article 2.2 of Directive 2005/62/EC.

The working group will be tasked to:

- compare Directive 2005/62/EC with the 16th CoE Guide
- identify differences between the Directive and the Guide and develop joint proposals for EC and CoE guidelines
- Prepare the chapter on QMS in the 17th edition of the Guide
- Dissemination of the guidelines following endorsement by the blood NCAs and CD-P-TS

The WG has been appointed for 2 years from June 2011 with a target for adoption of the guidelines by the end of 2012, with a training workshop in Q1 of 2013.

The scope of this WG is to look at Chapter 1 of the Guide and to harmonise the text of the 'Standards' with that of Directive 2005/62/EC. The current project will not extend into latter Chapters in the Guide such as donor selection. However, the EC has expressed a wish for inconsistencies between the Directives and the Guide to be identified – which may be the subject of future projects.

3.6 Recommendations on Donor Height and Weight – JPAC 11-10 – item 4.7

After approval at the last JPAC meeting this paper had been submitted to the UKBTS Forum meeting on 17 June.

UK BTS Forum had several concerns and was worried about the loss of donors. They asked for more firm data from each of the UK Countries on the projected losses, and would like operational input.

The Chair of SACCSD was disappointed that these questions were not raised when the paper was submitted to JPAC in March rather than the UK BTS Forum.

LW asked SB to produce a short update paper on how "Club '96 Donors" (Donors born after 1996 who are considered low risk for vCJD) and this recommendation might work together. She asked each Blood Service to take this opportunity to discuss this further with their operational leads and Chief Executives before it is resubmitted to the UK BTS Forum in September.

SB informed JPAC that she can give an age profile for NHSBT (England) donors, but not the other UK Countries.

Post Meeting Note: This paper was submitted to the UK BTS Forum meeting

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on 16 September 2011.

The 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 and that a Change Notification should be issued. **SB**

3.7 Assessing the uncertainty in the UK residual risk estimate model for blood donors – JPAC 11-12 – item 5.2

The proposal in the paper was to present residual risk estimates as 95% interval estimates, to present the data for the UK as a whole and on a rolling 6 year period. At the moment the proposal is only for blood donors.

Traditionally SACTTI reviews the parameters early in the year. The risk estimates are then produced by the Epidemiology Group and signed off by SACTTI, usually in October.

PEH informed JPAC that to produce risk estimates in the new format requires input from the NHSBT Audit and Statistics Department, but staff shortages will leave the Unit severely stretched. PEH believes that there is a business case in preparation to enable this work to proceed.

PEH also informed JPAC that it is highly unlikely that they could convert earlier years information into the proposed new format

PY arrived 11:29

Action: SM to liaise with PEH on how JPAC can help progress this further. **PEH & SM**

3.8 Revised Chapter 7 of the Red Book – JPAC 11-14 – item 6.2

The action was for CP to seek permission from Blackwells to reproduce "Figure 1" on page 3. CJS to ask RC if this had been done. **CJS**

3.9 Prion reduced red cell concentrates – quality monitoring – JPAC 11-15 – item 6.3

ST had taken this paper to the Prion Working Group where it was approved. The SACBC Chair, RC, will finalise the component specification which will be posted in a new trial component section on the JPAC website.

Post Meeting Note: The new specification has been received and will be posted in the new trial component section on the JPAC website when it is available.

3.10 Prion reduced red cell concentrates for exchange transfusion – JPAC 11-24 – item 6.4

As with the above item ST had taken this paper to the Prion Working Group where it was approved. The SACBC Chair, RC, will finalise the component specification which will be posted in a new trial component section on the JPAC website.

Post Meeting Note: The new specification has been received and will be posted in the new trial component section on the JPAC website when it is available.

ACTION

3.11 Blood Components – Proposed model for SNOMED-CT – JPAC 11-26 – item 7.1

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**

4. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

4.1 Borrelia burgdorferi (Lyme disease) risk assessment, version 1 - JPAC 11-30

JPAC approved the recommendation that no specific measures are needed in view of the lack of evidence of transfusion-transmitted infection other than the recall of blood components donated within 28 days of diagnosis of acute infection if notified.

4.2 Chikungunya Virus risk assessment, version 3 – JPAC 11-31

The situation regarding Chikungunya virus has not changed since SACTTI made its recommendations to JPAC in 2006 with respect to the outbreak in the Indian Ocean Islands. New outbreaks elsewhere, not covered by existing travel donor deferrals, would need to be handled similarly.

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

4.3 Crimean-Congo Haemorrhagic Fever Virus (CCHF) risk assessment, version 3 – JPAC 11-32

There have been limited outbreaks worldwide. This risk assessment has been updated with information on the outbreaks in areas of central Asia/Balkans.

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. Blood Services should be aware that travel patterns in the population may change over the years, but currently there is no evidence of a risk to the blood supply. SACTTI wanted it to be noted that travel patterns of the population may change and currently decisions are based on the NHSBT travel survey, which mirrored data from the International Passenger Survey.

PEH will correct the title on the summary sheet to “Crimean Congo Haemorrhagic Fever (CCHF)” and send to CJS who will recirculate to JPAC members marked “amended”.

Post Meeting Note: JPAC 11-32 Amended was circulated to JPAC on 8 July 2011.

4.4 Human Herpesvirus-8 risk assessment, version 3 – JPAC 11-33

ACTION

This risk assessment has been updated with the most recent references, which back up previous information in the assessment. No new information has come to light to change the recommendation.

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

Any decision, in the light of the SABTO review of MSM and donor deferral, may require the situation to be revisited.

4.5 Human Partetra Virus (HPTV) previously known as human parvovirus PARV4, risk assessment, version 2 – JPAC 11-34

PEH informed JPAC that little has changed since the risk assessment was first produced in 2008, but information from a 2010 International Workshop has been added.

JPAC endorsed recommendation to keep the situation, with respect to HPTV, under review and to revise the risk assessment as/when new information becomes available.

4.6 Severe Acute Respiratory Syndrome (SARS) risk assessment – update – JPAC 11-35

SACTTI reviewed the situation with regard to SARS at its June 2011 meeting. There has been no recent SARS activity world-wide.

JPAC noted that SACTTI will not be reviewing this risk assessment unless/ until a further outbreak of SARS occurs.

4.7 Simian Foamy Virus risk assessment, version 2 – JPAC 11-36

After a very lengthy discussion, when this last came to JPAC 2 years ago, it was decided not to take any action.

JPAC noted that there has been no change in the situation since the last update, and endorsed the recommendation to keep a watching brief and take no further action at this time.

4.8 Xenotrophic murine leukaemia related virus (XMRV) and other murine retroviruses risk assessment version 3 – JPAC 11-37

PEH informed JPAC that this risk assessment needs 2 minor amendments which were agreed at the recent SACTTI meeting.

JPAC endorsed the risk assessment (with the 2 amendments) and advised the UK Blood Services that there is no evidence that XMRV/ other murine retroviruses currently present a risk to UK supplies of blood, tissues, or organs.

PEH will update the risk assessment and send to CJS to recirculate to JPAC members marked “amended”. **PEH & CJS**

4.9 JPAC Position Statement on Emerging Infections – JPAC 11-38

Questions relating to managing the threat of new/emerging infections and their possible impact on the blood supply are regularly received by the Blood Services and JPAC, some of which (e.g. Parliamentary Questions), require a

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response in a very short time-frame. This position statement was designed to be used to respond these enquiries/ questions, ensuring that a consistent response is being supplied within a short time frame.

JPAC approved the publication of the emerging infection position statement on the JPAC website.

It was noted that it should say Emerging Infectious Diseases (EID) in the first paragraph. PEH will correct the position statement and send to CJS who will recirculate to JPAC members marked "amended".

Post Meeting Note: JPAC 11-38 Amended was circulated to JPAC on 8 July 2011 and the Position Statement was posted on the JPAC website on 20 July 2011.

4.10 West Nile Virus precautions for UK blood donors: starting date for donor deferral – JPAC 11-39

When reviewing the SACTTI WNV position statement it was noted that the start date for deferral was 1 April. This was applied as a precautionary approach in 2003.

The FDA CBER specify the "typical WNV season" as falling between 1 May and 30 November and the HPA starts its surveillance on 1 June each year.

SACTTI have looked at this issue again and feel there is no evidence to support a start date of 1 April.

JPAC endorsed the recommendation to follow WNV precautions for affected areas from 1 May to 30 November from 2012 onwards; not withstanding testing might be introduced. A Change Notification will be issued in early 2012. **SB**

Post Meeting Note: JPAC 11-39 was amended with the following information and recirculated to JPAC on 8 July:

- *The title changed to "Dates for operation of WNV precautions for UK donors.*
- *Added "as required by BSQR".*
- *Added additional paragraph at the end of "Brief summary" regarding end date in Europe.*

4.11 SACTTI advice re measles and blood donation – JPAC 11-40

There is large measles outbreak in France and other parts of continental Europe.

Although SACTTI recommends no additional donor selection measures at this time, it was thought that the information in this summary would be helpful to the Blood Services.

JPAC noted the content and 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.

PY asked for the word "blood" to be removed from the title or tissues and cells added. PEH will update the summary and send to CJS who will recirculate to

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JPAC members marked “amended”.

Post Meeting Note: JPAC 11-40 Amended was circulated to JPAC on 8 July 2011.

4.12 UK residual risk estimate model for blood donors – JPAC 11-41

The residual risk estimate model for blood donors for the UK came from Kate Soldan originally in 2003. Every year SACTTI review the parameters that are being used.

It was agreed by JPAC that in future the residual risk calculations would make use of interval estimates, which represent an advance in the methodological approach and that inclusion of interval estimates would enable the reader to understand that the actual risk lies somewhere between two values.

SACTTI has had further discussions about the parameters used for the risk estimate model and has now decided that the elements for error and test sensitivity will be dropped in future calculations. This would reduce much of the complexity and make the estimates compatible with those produced by other blood services.

JPAC endorsed the proposal to drop the elements for error and test sensitivity which has previously been included in the residual risk estimates.

5. STANDING ADVISORY COMMITTEE ON TISSUE AND CELLULAR THERAPY PRODUCTS

5.1 Recommendation for a change to the Live Tissue Donor Selection guidance for ‘Malaria’ – JPAC 11-42

JPAC approved the recommendation from SAC-TCTP that the surgical donor guidelines be amended and brought onto line with the deceased donor guidelines with regard to malaria.

Post Meeting Note: Change Notification No 14 2011 – Malaria, Live Tissue Donors, was issued on 1 September 2011.

6. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

6.1 Guidance on deviations from the specified storage temperature for Fresh-Frozen Plasma (FFP) whilst in its frozen state – JPAC 11-43

It was agreed that this paper provided useful information to help local establishments produce a risk assessment for the situation when freezers containing FFP fail. SACBC was asked to amend the paper to include the need for local risk assessments. The revised paper will be reviewed by the next JPAC EWG and, if approved, posted on the JPAC website.

Post Meeting Note: This was reviewed and approved at the JPAC EWG on 22 September and has been posted in the Document Library on the JPAC Website.

6.2 Labelling of blood components

SACBC raised the question regarding the use of the wording "Risk of adverse

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reaction/infection, including vCJD" (which will be inserted into the specification for every blood component in the 8th Edition of the Red Book) on components imported from countries with low risk of 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 will need to redraft the specification for these components to ensure that they are sourced from a low-risk area. **RC**

6.3 Prion filters

The current contract for prion filters will be ending within the year and therefore tender documents are being prepared. SACBC will revise the relevant specifications on the JPAC website: **RC**

- UKBTS General Information 06 – Evaluation of Efficacy of Prion Removal Filters
- UKBTS General Information 07 – Validation of Blood Component Quality Following Prion Removal Procedures for Red Cell Components

7. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

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

There was considerable discussion on this paper. SB was asked to provide further information on definitions of severity of heart disease. **SB**

7.2 JPAC Safety Framework completed for ischemic heart disease – JPAC 11-45

See item 9.

8. UK BLOOD SERVICES QUALITY REGULATORY GROUP

8.1 UK BTS Quality and Regulatory Group – Terms of Reference – JPAC 11-46

IB had submitted the terms of reference to JPAC. The Medical Directors informed IB that these should be submitted to the UK BTS Forum along with an annual report.

8.2 UK BTS Quality and Regulatory Group – Minutes from the meetings on 7 January 2011 (approved) and 18 March 2011 (draft) – JPAC 11-47

It was agreed that the minutes of the UK BTS Quality and Regulatory Group meetings will be circulated to JPAC for information.

9. JPAC SAFETY FRAMEWORK TEMPLATE – JPAC 11-48

After a short discussion it was agreed that SM should review the template further before taking this to the UK BTS Forum for a decision on whether JPAC should have its own safety framework.

ACTION

Post Meeting Note: This will now be know as the JPAC Decision Making Framework. This was discussed at the UK BTS Forum on 16 September. LW clarified that her concern about the draft framework was the inclusion of cost effectiveness analysis. SM agreed to produce a paper for the next UK BTS Forum meeting in December. **SM**

10. JPAC WORK PLAN 2011/2012 – JPAC 11-49

The JPAC workplan had been submitted to the UKBTS Forum (UKF) meeting in June. RJ and LW confirmed that the UKF members had no additional items to add and the workplan was approved.

11. JPAC WEBSITE TRANSFUSIONGUIDELINES.ORG.UK

11.1 Website Manager Post – update

2 applicants for the post had been interviewed on Wednesday 22 June and a further 4 were due to be interview on Friday 8 July.

12. COE 16TH EDITION

12.1 Gap analysis between the Red Book and the CoE guide

SM has asked the relevant SAC chairs to do a gap analysis between the 16th Edition of the EDQM Guide to the preparation, use and quality assurance of blood components and the chapters they are preparing for the new edition Red Book.

13. UK BTS FORUM

There had been considerable discussion about Club 96 donors (those born after 1996, and so not exposed to a dietary risk of vCJD) and how their donations might be utilized as a risk reduction measure for vCJD.

14. SaBTO

LW gave the SaBTO report.

14.1 MSM

SaBTO reached a firm recommendation at its meeting in May which has gone to the UK Health Ministers.

14.2 CMV

SaBTO are reviewing the need for CMV serology testing in addition to universal leucodepletion to prevent CMV transmission and should make a decision on this at their meeting in September.

PEH noted that if a new recommendation was made then the JPAC Position Statement on CMV would need to be reviewed.

ACTION

14.3 vCJD

A review of the assumptions around the current risk of vCJD in the UK will be discussed in the first meeting of the Advisory Committee on Dangerous Pathogens (ACDP) TSE subgroup on 14 July 2011. Any conclusions will be referred to SaBTO in January 2012.

14.4 SaBTO Public Meeting

The public meeting in October will be on "Consent for transfusion".

PEH and LW left the meeting at 14:30

15. ANY OTHER BUSINESS

15.1 Haemovigilance meeting 24 June 2011

On behalf of the UK BTS Forum LW had attended a Haemovigilance meeting held at the Royal College of Pathologists on 24 June.

This meeting included both SHOT and the MHRA and explored joint working. There was agreement that it would be sensible to explore the idea of a common database from which SHOT and MHRA could both pull data and this will be further discussed.

Dr Paula Bolton-Maggs will replace Dr Clare Taylor as Medical Director of SHOT and Chair of the Working Expert Group. Dr Sue Knowles had done an excellent job in the interim.

The meeting concluded at: 14:36

16. DATE & VENUE FOR FUTURE JPAC MEETINGS

2011

- Thursday 10 November - Association of Anaesthetists, London

2012

- Thursday 8 March - Association of Anaesthetists, London
- Thursday 28 June - Association of Anaesthetists, London
- Thursday 8 November - Association of Anaesthetists, London