APPROVED 13/11/2008

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 40th Meeting held at the Novartis Foundation, 41 Portland Place, London, on Thursday 26th June 2008

Meeting commenced at 10:50

PRESENT

Dr Rebecca Cardigan	**(RC)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO **(Observer)**
Dr Bruce Cuthbertson	**(BC)**	-	Representing the Quality Managers of the 4 UK Blood Services
Prof. Ian Franklin	**(IMF)**	-	Medical Director, Scottish National Blood Transfusion Service
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
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	**(SM)**	-	Standing Advisory Committee on Blood Components
Dr Brian McClelland	**(BMc)**	-	Professional Director of JPAC **(Chair)**
Dr Willie Murphy	**(WM)**	-	National Medical Director, Irish Blood Transfusion Service **(Observer)**
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Prof. Stan Urbaniak	**(SU)**	-	Standing Advisory Committee on Immunohaematology
Dr Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant
Dr Nay Win	**(NW)**	-	Observer
Dr Phil Yates	**(PY)**	-	Standing Advisory Committee on Tissues

WELCOME

The Chair of JPAC welcomed Linda Lodge, the new Chair of the SAC-IT, to her first JPAC meeting.

Action

1. APOLOGIES

Morag Ferguson	**(MF)**	-	National Institute for Biological Standards and Control
Dr Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Dr Morris McClelland	**(MM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Derwood Pamphilon	**(DP)**	-	Standing Advisory Committee on Stem Cells
Prof. David Pegg	**(DPg)**	-	Incoming Chair of the SAC on Tissues
Mr Chris Rudge	**(CR)**	-	Medical Director, UK Transplant

2. NEW SAC CHAIRS

The Chair of JPAC reported that the following had agreed to be nominated as SAC Chairs:

Dr Chris Prowse – SAC on Blood Components
Dr Nay Win – SAC on Immunohaematology

Action

Dr Rachel Green – SAC on Stem Cells

It was proposed that the procedure for the appointment of SAC Chairs should be reviewed to ensure a transparent process of advertising and selection.

The Chair of JPAC noted that this was his last meeting and that SM will be acting Chair from August 1st 2008 until a new appointment is made.

Chair of JPAC

LW updated the committee on the arrangements. She noted the intention of the UKBTS Forum to commission a further review of the position, roles and responsibilities of JPAC.

3. MINUTES OF THE MEETING 6TH MARCH 2008 – JPAC 08-38

The draft minutes had been circulated and all comments received incorporated.

The following additional comments were made:

Item 3.2. paragraph 2, line 2 delete "on behalf of the UK Blood Services"

Item 6.1. page 5 para 5, line 2, delete "it would" and substitute "it may".

Item 6.2. page 6, replace "LCMV" with "Lymphocytic Choriomeningitis Virus (LCMV)"

Item 8.2. last sentence. Delete last sentence and replace with "There are currently no prospective studies of unreported adverse events or reactions that occur once a donor has left the donor session."

Item 6.7. delete Chikungunya paragraph and replace with information on West Nile Virus.

4. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 08-39

4.1 Item 6.3. (Risk Assessment on Severe Acute Respiratory Syndrome [SARS] Virus)

It was noted that this document contains specific recommendations about the need for a reliable system for responding rapidly to outbreaks. This had been discussed on previous occasions by both JPAC and the UKBTS Forum. No definitive arrangements had been put in place and, in the event of an outbreak requiring urgent consultation and action, there would be a heavy dependence on the Chair of SACTTI.

LW suggested that this matter should be included in the remit for the planned review of JPAC and that the existing NBS/HPA infection surveillance programme may provide the basis on which a rapid response mechanism could be built.

It was also noted that there may be delays in implementing risk reduction measures. The UKBTS Forum has made a decision that in future Change Notifications will generally carry an implementation date. Since this may lead to scrutiny by the regulator, it will be important to develop a mechanism to ensure that implementation dates can be complied with.

Action

4.2 Chikungunya – item 6.7

See item 3.

4.3. "Red Book" Chapters 12 to 18 & Annex 1 (Immunohaematology) – item 9.5.

The outgoing Chair of SACIH confirmed that the this committee had consulted and concluded that there was a continuing need for the Immunohaematology sections in the Red Book and that he would brief the new Chair on the details.

4.4. Risk Framework – item 9.6.

This item is on the SaBTO work programme.

5. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

5.1. Components in Neonatal Recipients: Guidelines for UK Blood Transfusion Services - Section 8.18: "Components suitable for use in intrauterine transfusion, neonates and infants under one year" – JPAC 08-40

SACTTI had noted that Section 8.18 of the Guidelines for the UK Blood Services (Red Book) contained specific requirements for blood donations for use in IUT, neonates and infants under one year, which were not consistent with Section 10.5. This text first appeared in the Red Book, 3rd Edition (1996). Members were uncertain where this text had originated.

Action: SM to draft a Change Notification to removed this inconsistency **SM**

Post Meeting Note: From British Journal of Haematology, 124, 433-453 Transfusion guidelines for neonates and older children.

1.1.1. Donors

Components for transfusion *in utero* or to children under 1 year of age must be prepared from blood donated by donors who have given at least one previous donation within the past 2 years, which was negative for all mandatory microbiological markers.

5.2. UK Blood Services submission to European Directive Re: West Nile Virus donor deferral (Annex III, section 2.2.1) – JPAC 08-41

Chair of SACTTI presented the proposal that the specific reference to West Nile Virus should be removed from section 2.2.1. of Annex 3 (Infection) of the Blood Safety and Quality Regulation (BSQR) since it is covered by section 2.3. (deferral for particular epidemiological situations).

Since this paragraph is a transposition from the Commission Directive 2004/33/EC it would be necessary to raise this proposal through the Competent Authority. This change would provide consistency in the event of outbreaks of other potentially transmitted transfusion infections which would also be covered by section 2.3. A similar argument applies to Malaria.

JPAC endorsed the proposal.

Action: JPAC Chair raise/write to:- MHRA, Secretariat of CD-P-TS and EBA. **BMc**

Action

5.3. SACTTI HTLV Discussion Paper: Review of HTLV testing within the UK Blood Services – JPAC 08-42

This discussion paper had been prepared by SACTTI to identify future options for HTLV antibody testing of donations in the event that the current practice of preparing pooled donor samples for testing is terminated.

The options thereafter would be:

(1) test all donations for HTLV antibody using single (unpooled) donation samples.

(2) Selective testing – restricted to previously untested donors – using unpooled donation samples.

(3) Cease HTLV antibody screening (it is not required by the BSQR)

(4) Continue to prepare pools purely for HTLV antibody testing.

JPAC endorsed the recommendation to continue HTLV testing of pools of blood samples while pools are required for NAT testing, and that the UK blood services should evaluate the operational feasibility and comparative cost of individual testing of previously untested donors if/when pool preparation is no longer required for NAT testing. JPAC noted that in option (2) it would essential to have an unambiguous definition of "previously untested donor".

It was suggested that the review might consider aspects such as: effect on estimated residual risk, cost, impact on supply, and IT implications.

Action: SM to be included in the JPAC report to the UK BTS Forum (05-12-08) **SM**

5.4. Discussion Paper: Foreign travel, tropical areas and donor selection – JPAC 08-43

JPAC endorsed the recommendation that plans should be developed "to conduct, as a priority, a survey of attending blood donors to provide data on recent foreign travel and countries visited, so that the likely impact of any additional travel-related donor deferrals can be more accurately predicted, and the risk of imported infections with a risk of transfusion-transmission better understood."

Action: LW and PEH **LW & PEH**

5.5. Human Parvovirus PARV4 – Risk Assessment – JPAC 08-44

JPAC endorsed the risk assessment and the recommendation to keep this agent under review. It was suggested that the risk assessment could contain a more explicit statement about the lack of any evidence for pathogenicity of this agent.

Action: PEH **PEH**

It was noted that there is a funded European study that is collecting information and samples for the purpose of studying donor-to-recipient transmission of infections and that they could be approached to explore obtaining transmission data for PARV4.

5.6. vCJD Risk Assessment – update

This risk assessment has been reviewed and it was not felt that any revision was necessary.

6. STANDING ADVISORY COMMITTEE ON TISSUES – PHIL YATES

Action

6.1 A proposal to remove endoscopy as a deferral criteria for tissue donors (v1) – JPAC 08-45 and
The negative impact of endoscopy on eye donation (to accompany the above) – JPAC 08-46

JPAC thanked Dr Yates for this very useful paper (JPAC 08-45) and Mr Kaye and Prof Armitage for paper JPAC 08-46, detailing the impact of the "endoscopy deferral on the availability of corneas for transplantation."

It was emphasised that the Tissues Directive (Commission Directive 2006/17/EC for human tissues and cells) does not contain any reference to endoscopy as a deferral criterion.

JPAC approved the proposal that a Correction Notice with regard to the Deceased Donor DSG be issued rapidly to withdraw the endoscopy deferral requirement.

Action: Phil Yates

Post Meeting Note: *Change Notification No 3 2008 – Endoscopy – Tissue Donor Selection Guidelines – Deceased Donors was issued on 3rd July 2008*

In view of the evidence that had been presented by Dr Yates it was agreed that SACTTI should be requested to further examine the evidence on risks of transmission by endoscopy and consider the possibility of a recommendation to relax this requirement for whole blood and other donor categories.

PEH

Action: PEH

7. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

7.1 Post-thaw stability of fresh frozen plasma – JPAC 08-47

JPAC endorsed the proposals:

1) that further studies should be undertaken on the properties of thawed fresh frozen plasma during extended periods of liquid storage. **Action**: SM **SM**
2) that further consultation with users be carried out to identify likely clinical indications and demand. **Action:** DN **DN**

7.2. Irradiation of red cells remanufactured into SAG-M – JPAC 08-48

JPAC thanked SACBC for the excellent paper and endorsed the recommendations:

(a) "Red cells stored in CPD plasma can be re-manufactured at day 5 of storage to red cells in SAG-M and this product should have the same specification and shelf life of standard red cells in SAG-M.

(b) Leucocyte depleted whole blood anticoagulated with CPD can be stored at 4^0C for up to 5 days prior to the production of red cells in SAG-M".

7.3. Discard limits for blood components – JPAC 08-49

There was extensive discussion of this paper during which the following points were raised.

Action

- There was some concern that the purpose of the proposal was to solve a difficult problem of what to do with one of the small percentage of component units selected for QA testing when it was found to lay outside specification.
- Concern was also expressed about a requirement that would lead to discard of a blood component that could provide a clinically appropriate dose for (e.g. a patient with low body weight).
- It was accepted that there must be levels below or above which a component will fail quality requirements
- Options discussed included adding to the label "subject to biological variability" or labelling with the haemoglobin content.

Action: Chair of SACBC agreed to get further consideration and resubmit the proposal in due course. **SM**

7.4. X-ray irradiation of red cells in SAG-M – JPAC 08-50

SACBC had previous submitted paper JPAC 07-20 X-ray irradiation of blood components to JPAC on 1st March 2007. JPAC approved the proposal from SACBC that validation of this device should be undertaken by UKBTS.

JPAC welcomed this report. Noted that x-ray irradiation of red cells in SAG-M caused a similar potassium leakage and haemolysis as gamma irradiation and endorsed the proposal that the Raycell X-ray irradiator used as described in paragraph 4.1. of the paper JPAC 08-50 be accepted as an alternative to gamma irradiation for red cells.

7.5. Change in specification for platelets resuspended in 100% Platelet Suspension Medium ("washed platelets") – JPAC 08-51

It was emphasised that this paper applies specifically to "washed platelets" i.e. re-suspended in 100% platelet suspension medium. Blood Establishments have reported continuing difficulties in achieving the platelet level of 240 x 10^9 per pack.

JPAC approved the proposal that the specification for this product should be lowered from 240 down to 200 x 10^9 per pack.

Action: SM to draft the Change Notification

Post Meeting Note: Change Notification No. 4 2008 - Platelets suspended in additive solution, leucocyte depleted – issued 21st July 2008

7.6. Pathogen inactivation – verbal update

LW gave a brief report on work being undertaken by NHSBT and the Department of Health's Analytical Team on assessment on the risks, benefits and costs of pathogen reduction technologies in the context of other risk reduction measures.

This was one of three topics raised in a tabled draft letter (**JPAC 08-62)** raising issues for consideration by SaBTO. JPAC supported the proposal to send this letter to Mr William Connon of DH.

SM to provide a briefing note on the NHSBT programme for the UK BTS Forum meeting in September. **Action:** SM

Post Meeting Note: This item was included in the JPAC report to the UK BTS Forum meeting on 5th September.

Action

8. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

8.1. Portfolio of Blood Components for use by the 4 UK Blood Services: update – JPAC 08-52

LL gave a progress report on the development of the database for the Common Portfolio of Blood Components.

9. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

9.1. Draft recommendation for removal of the upper age limit for re-attending whole blood and component donors – JPAC 08-61

JPAC approved this paper in principle. It could be approved following circulation to members of a further draft containing the additional independent medical opinions, consideration of the 1995 American Red Cross paper on Donor Adverse Events, some expansion of the section on component donations (6.3), a re-ordering of section 6. to put the current item 6.2 as item 6.1.

Other suggestions were to include some recommendations on monitoring adverse events and to consider whether reference should be made to the need (or lack of need) to make any additional clinical observations during the assessment of older donors.

Action: BMc **BMc**

9.2. Workshop on management of haemoglobin and iron in blood

This workshop had taken place on 10th June 2008.

9.3. Draft minutes from the SACCSD meeting held on 30th April 2008 – JPAC 08-53

Circulated for information.

10. ADVISORY COMMITTEE ON THE SAFETY OF BLOOD, TISSUES & ORGANS

10.1. SaBTO Work Plan, April 2008 – October 2009 – JPAC 08-54

Circulated for information.

10.2. Summary of the SaBTO meeting held on 23rd January 2008 – JPAC 08-55

Circulated for information.

10.3. Summary of the SaBTO meeting held on 29th April 2008 – JPAC 08-56

Circulated for information.

10.4. Draft letter to William Connon – JPAC 08-62

See item 7.6.

11. UKBTS FORUM

11.1. Professional Director of JPAC

Action

See item 2.

12. JPAC CHAIRMAN'S REPORT

12.1. Implementation Dates on Change Notifications

See item 4.1., last paragraph.

13. ANY OTHER BUSINESS

13.1. Medical Director UK Transplant

LW informed JPAC that Mr Chris Rudge was moving to the Department of Health as national Clinical Director for Transplantation, and that there will be a new Associate Medical Director for Organ Donation and Transplantation within NHS Blood and Transplant.

It was agreed that a solid organ transplant specialist should continue to be a member of JPAC.

The meeting concluded at 15:40

11. DATES AND VENUES OF FUTURE JPAC MEETINGS

- Thursday 13th November 2008 - The Novartis Foundation, London

Proposed dates for 2009

- Thursday 12th March - The Association of Anaesthetists, 21 Portland Place, London, W1B 1PT
- Thursday 9th July - The Association of Anaesthetists, 21 Portland Place, London, W1B 1PT
- Thursday 12th November - The Association of Anaesthetists, 21 Portland Place, London, W1B 1PT