Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 38th Meeting held at the
The Novartis Foundation, 41 Portland Place, London, on Thursday 21st June 2007

Meeting commenced at 10.50 am

PRESENT

Dr Stephen Field	**(SF)**	-	Deputising for Dr Richard Jones, WBS
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)**	-	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
Dr Derek Norfolk	**(DN)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Derwood Pamphilon	**(DP)**	-	Standing Advisory Committee on Stem Cells
Miss Caroline Smith	**(CJS)**	-	JPAC Manager (Minute taker)
Prof. Stan Urbaniak	**(SU)**	-	Standing Advisory Committee on Immunohaematology
Dr Lorna Williamson	**(LW)**	-	Interim Associate Medical Director, NHS Blood and Transplant

Welcome

The JPAC Chair welcomed Dr Stephen Field who was deputising for Dr Dick Jones.

Action

1. APOLOGIES

Dr Bruce Cuthbertson	**(BC)**	-	Representing the Quality Managers of the 4 UK Blood Services
Dr Morag Ferguson	**(MF)**	-	National Institute for Biological Standards and Control
Prof. Ian Franklin	**(IMF)**	-	Medical Director, Scottish National Blood Transfusion Service
Dr George Galea	**(GG)**	-	Standing Advisory Committee on Tissues
Dr David Hutton	**(DH)**	-	Standing Advisory Committee on Care and Selection of Donors
Dr Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
Dr Morris McClelland	**(MM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Mr Stuart Penny	**(SP)**	-	Standing Advisory Committee on Information Technology
Mr Chris Rudge	**(CR)**	-	Medical Director, UK Transplant

2. MINUTES OF THE MEETING 1ST MARCH 2007

The minutes were approved with one amendment to the last paragraph in section 8.1.
"Also noted was the requirement for a review of the UK BTS policy that precludes the

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use of growth factor stimulation of healthy volunteer donors."

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 07-28

3.1. Component quality: reliability of leucocyte removal – item 3.2

It was agreed that a short document should be drafted attempting to summarise the position reached by JPAC taking into account the report that had been received from ESOR (Note on leucocyte depletion failure & vCJD JPAC 07-26).

Action: BMc to draft note for next JPAC meeting on 1st November 2007. **BMc**

There was agreement that leucocyte removal, like other blood safety measures, must be seen as a risk reduction step rather than having the potential to provide absolute safety.

Action: In discussion, JPAC requested that the Chair write to Prof. Lindsey Davies noting the value that JPAC members place on the work that has been done by ESOR analysts.

Post Meeting Note: Chair of JPAC wrote to Prof. Lindsey Davies 26th July 2007.

4. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

4.1. Sexual partners of individuals successfully treated for HCV infection: eligibility as blood donors – JPAC 07-29 (updated)

JPAC endorsed the recommendation in this paper for an amended DSG entry. JPAC also endorsed the recommendation to adjust the wording throughout the DSGs to refer to "person(s) infected with hepatitis C virus".

Action: Issue Change Notification. CJS to investigate and report to JPAC Chair on the best method to ensure comprehensive "global" change of terminology throughout all DSGs.

Post Meeting Note: Change Notification sent to Medical Directors for approval 24th September 2007. All the instances of "HCV positive individuals" have been edited to read "person or person(s), as appropriate, infected with hepatitis C virus".

4.2. vCJD risk assessment – JPAC 07-30

JPAC endorsed this statement as a useful summary of current information and made the following points.

- While approving in principle the proposal to publish this risk assessment on the website, JPAC requested that the wording be thoroughly reviewed with respect to its clarity for a potential web audience and its consistency with the current position statement.

  Action: Members agreed to send comments to PEH. **ALL**

- Some members commented on the format of the risk assessment, noting that most of the important content is in the "free text" sections, that the check boxes were in some cases confusing and that it would be valuable to attempt some degree of quantitation of risk benefits etc. since this would increase the usefulness of these documents in any structured decision making processes.

Action

- It was noted that the format of the risk assessment had not been designed with prion infection in mind.

4.3. Change to DSG entry on donors with a history of jaundice – JPAC 07-31

SACTTI considered this advice again in April and confirmed that their original recommendation (JPAC 07-31) still stands. JPAC endorsed this recommendation.

Action: Issue Change Notification. **CJS**
DSG to be amended according to JPAC 07-31. **DH**

Post Meeting Note: The recommendation in this paper is for "Hepatitis of unknown origin".

4.4. Surveillance of new and emerging pathogens

The Chair of SACTTI reported on constructive discussions with HPA (Dr David Brown) which should lead to sharing of new information and risk assessments for new and emerging infections between SACTTI, NEPNEI and HPA.

Action: Brief report on new arrangements for surveillance will be provided for a forthcoming JPAC meeting **PEH**

4.5 Foresight Project

The JPAC Chair undertook to provide PEH with the relevant reports from the DoH Foresight Project which had addressed a number of relevant issues concerning new and emerging infections.

Post Meeting Note: BMc has provided PEH with the reports

5. STANDING ADVISORY COMMITTEE ON STEM CELLS

5.1. JPAC Discussion Document: The use of G-CSF in volunteer donors – JPAC 07-32

Chair of SACSC had provided a review of the use of G-CSF in donors focusing on donor safety issues. It was agreed that the text and title would be adjusted to cover only stem cell donors. With this modification the paper was approved by JPAC. **DP**

Action: Seek formal approval from the author DP for publication as a position statement on JPAC website. If this might interfere with publication, request a one-page summary from DP for web publication. **DP**

Post Meeting Note: DP has submitted this paper for publication and therefore will not be posted on the website.

There was discussion about the clarity of the current UK BTS policies regarding G-CSF stimulation of donors prior to granulocyte collection by apheresis.

Action: The documentation of the current UK BTS position to be reviewed and brief summary circulated. **BMc**

6. STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE

6.1. Transfusion strategies in haemoglobinopathy patients – JPAC 07-33

Action

Chair of SACCTM had prepared this paper with particular reference to the potential for an increase in donor exposure to red cell units as a result of further reductions in red cell content due to new prion filtration procedures.

JPAC welcomed this very useful summary and approved its submission to the Prion Reduction Working Group as a contribution to the risk assessment process and also to the NBS Component Donation Project, via Dr Angus Wells. **DN**

There were three recommendations:

(1) ensure hospital transfusion laboratories can readily identify red cell units with higher red cell and Hb content (e.g. concentrates from "Top and Top" units)

(2) target the use of apheresis red cells with higher (and standardised) haemoglobin content to transfusion dependent patients (the UK Haemoglobinopathy Forum are interested in pursuing clinical studies)

(3) double-dose red cell collections, presumably from larger male donors, could also be allocated to individual transfusion-dependent patients (routine provision could, theoretically, halve donor exposures)

It was noted that NBS were pursuing recommendations 2 and 3 and that it may be helpful to draw this to the attention of the other 3 UK Blood Services.

Action: JPAC Chair to inform the Medical Directors of the other Services that the NBS is developing an active programme to develop options 2 and 3.

Post Meeting Note: Chair of JPAC wrote to the Medical Directors on 26th July 2007.

It was also noted that the Red Book 7th Edition contains a brief section on red cell donation by apheresis and that this should be reviewed by the SACCSD for the next edition.

Action: Chair of SACCSD **DH**

7. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

7.1. Proposed revision of specification for MB treated and removed FFP, non-UK – JPAC 07-34

Both papers attached in JPAC 07-34 were considered by MSBTO at their January 2007 meeting and were approved amending the specification for imported FFP for children. This was brought to JPAC for information, as it is a change to the Red Book guidelines. DN informed the group that this was discussed by the BCSH blood transfusion task force, as it is also a change in their guidelines.

Action: Issue Change Notification.

Post Meeting Note: Change Notification No. 4 2007 – Specification for methylene blue treated and removed FFP, non-UK issued 20th September 2007.

7.2. Quality of red cells for exchange transfusion and their re-manufacture to red cells in SAG-M – JPAC 07-35

JPAC discussed this paper and accepted its recommendations with one reservation concerning the behaviour of remanufactured red cells that were subject to gamma irradiation. The proposal was accepted on the basis that implementation would be

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commenced in one location only and that an evaluation of irradiated remanufactured red cells would be completed and evaluated by SACBC before implementing the process in any other location.

7.3. Platelet storage temperature limits V.3 – JPAC 07-36

Post Meeting Note: The title of this paper has been changed to "The effect of temperature excursions on platelet quality".

This paper previously been discussed at JPAC. Further advice had been received from SACTTI about the potential impact of raised storage temperature on bacterial growth and has been incorporated into the paper.

JPAC approved the document (subject to the edits suggested) to be used as a source of information for Service Medical Directors, or their delegates, in situations where the risk of a concessionary release requires to be assessed.

Action: JPAC Chair to send to Medical Directors and the UK BTS Forum with covering note emphasising that this is not intended as guidance but as background information that may be used in a risk assessment.

Post Meeting Note: This renamed updated paper "The effect of temperature excursions on platelet quality" was sent to the Medical Directors of the 4 Blood Services and the UKBTS Forum on 13th July 2007 emphasising the above.

JPAC also agreed that it would be useful to submit an article (probably an editorial) to a peer review journal to encourage professional discussion of the issues involved. It was suggested that Dr James P AuBuchon (Dartmouth-Hitchcock Medical Centre, Lebanon, New Hampshire, USA) might be interested to prepare such a piece.

Post Meeting Note: This renamed updated paper "The effect of temperature excursions on platelet quality" has been sent to Dr James AuBuchon.

7.4. JPAC workshop to develop a common UK blood component catalogue – JPAC 07-37

Chair of SACBC gave a progress report. The aim of the workshop was to decide which components we should retain which we should phase out and new components that warranted inclusion in the portfolio.

Next steps:

- CJS to circulate to JPAC nomenclature of components
- SACIT to establish common UKBTS codes for all components in the portfolio.
- CJS will continue work on the format of the portfolio
- Consultation on the draft portfolio (this doesn't need to include the product codes)
- Consultation – send to the National Transfusion Committee for dissemination to the Regional Transfusion committees.

Post Meeting Note: Nomenclature of components circulated to JPAC on 22nd June 2007

7.5. Briefing paper on review of SPC methodology for monitoring conformance to specification of blood components – JPAC 07-38a
&
JPAC SPC Task-Based Group: Statistical process control methods for monitoring blood products – circulated for information – JPAC 07-38b

The SPC sub-group had been set up by the Chair of SACBC who had enlisted the help

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of statisticians from UKT, NIBSC and NBS colleagues.

JPAC welcomed this very clear and informative document and recorded its thanks to all the members of the group and the parent organisations that had made their time available.

The JPAC Chair invited members, particularly those with access to relevant statistical expertise, to provide comments on the paper. **ALL**

JPAC noted the intention to carry out a pilot study to evaluate the utility of the alternative methods for SPC and that a protocol is being developed by the group.

It was also noted that this is a matter of considerable interest internationally and expressed the hope that the work, including the results of the evaluation, will be prepared and submitted for publication in a peer review journal.

It was further commented that there are important questions to be investigated about the accuracy of the measurements providing the raw data for SPC and suggested that this issue might usefully be referred to in any publication.

8. UKBTS FORUM

8.1. Abridged notes from UKBTS Forum meeting on 11th May 2007 – JPAC 07-39

JPAC received and noted this paper from Dr Dick Jones.

9. HAEMOCHROMATOSIS

This agenda item could not be dealt with in the absence of the member who had raised it.

10. PRION TESTING

10.1. Report from the UKBTS Forum vCJD Workshop held on 17th April 2007 – JPAC 07-40

It was reported that this meeting had been very productive and had generated a task list. The UK BTS Forum had set up a Prion Testing Working Group Chaired by Dr Marc Turner to deal with regulatory, operational and ethical issues expected to arise when a vCJD test for donor screening becomes available.

In discussion it was noted that the relationship of this new group to JPAC should be clarified.

Action: CJS to organise a teleconference – participants to include BMc, LW, PEH, Marc Turner and Phil Minor from NIBSC.

Post Meeting Note: A teleconference took place on Wednesday 22nd August 2007.

11. "RED BOOK" 7TH EDITION - ADDENDUM

11.1. It was reported that following a successful consultation the comments on the revised Chapters 21 to 24 have been collated and sent to the Chairs of SACT and SACSC.

Action: Chairs SACT and SACSC to ensure that finalised chapters are submitted to

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CJS.

Post Meeting Note: All relevant chapters received and sent to the TSO. Awaiting production schedule from TSO.

12. JPAC CHAIR'S REPORT

12.1. Proposal to change the remits of the SACCSD and SACTTI – JPAC 07-41

This paper had been approved at the JPAC Executive Working Group on 24th May. JPAC also gave its approval, suggesting some minor changes in wording which will be incorporated.

Action: JPAC Chair to discuss implementation with Chair of SACCSD who has been unable to attend the recent JPAC meetings. **BMc**

12.2. Council of Europe Activities in the Field of Blood Transfusion and Organ Transplantation

This item was deferred due to lack of time.

Action: JPAC Chair to brief SAC Chairs **BMc**
Agenda item for JPAC Executive Working Group on 4th October

Post Meeting Note: On agenda for October JPAC Executive WG Meeting.

12.3. MSBTO

It was reported that the new committee, to be appointed by the Public Appointments Commission, will be the Advisory Committee on the Safety of Blood, Tissues and Organs. It is hoped that its first meeting will be in the Autumn 2007. JPAC Chair undertook to seek clearance to make Terms of Reference available to JPAC members.

Action: JPAC Chair to write to William Connon at the Department of Health with regard to the Terms of Reference.

Post Meeting Note: Terms of Reference for the Advisory Committee on the Safety of Blood, Tissues and Organs (ACSBTO) circulated to JPAC 26th July 2007.

13. ANY OTHER BUSINESS

13.1. SACCSD

Chair of SACCSD had sent a note proposing to invite Dr Ingrid Wilson to join SACCSD. This was warmly welcomed by JPAC.

Post Meeting Note: JPAC Chair has informed DH that JPAC approved this proposal.

13.2. SACIH

Anti-A/B

Chair of SACIH has received an assurance from the director of the current provider that they will give us another batch, but he will ask him to write formally when it is constituted as an independent company.

13.3. People who present themselves to donate who have spouses from Sub Saharan Africa

Action

SF (deputising for Dr Dick Jones) informed JPAC that the WBS intended to raise, for discussion at a future meeting, some problems that have been raised by people who present themselves to donate who have spouses from Sub Saharan Africa.

The JPAC Chair requested that a brief paper be provided, specifying the issues on which advice is required.

Action: SF to provide a brief paper for JPAC. **SF**

13.4. Retirements

JPAC noted the retirements of Dr Elizabeth Love and Dr Elizabeth Caffrey and requested that the minutes record our appreciation to both these colleagues for all the hard work for JPAC.

13.5. Pathogen Inactivation

LW reported that an update day has been arranged by NBS and members of JPAC are invited to attend. It was also agreed that the consensus statement from the recent Canadian conference on pathogen inactivation would be circulated to JPAC. In discussion it was reported that some Services have concerns about the effectiveness of bacterial screening as a means of preventing platelet contamination reactions, and that this concern is leading to a renewal of interest in the PI option. Also noted that the Canadian Consensus supports pathogen inactivation as a general approach to reduce risks due to new and emerging infections.

Post Meeting Note: Circulated to JPAC 6th July 2007 (1) Briefing paper for MSBTO on bacterial contamination of platelet concentrates, bacterial screening and pathogen inactivation and (2) Pathogen Inactivation: Making decisions about new technologies – Preliminary report of a consensus conference.

The meeting concluded at 15:24

14. DATES AND VENUES OF FUTURE JPAC MEETINGS

- Thursday 1st November 2007 at the Novartis Foundation in London

2008

- Thursday 6th March 2008 – the Novartis Foundation, London
- Thursday 26th June 2008 – the Novartis Foundation, London
- Thursday 30th October 2008 – the Novartis Foundation, London