APPROVED 12/03/2009

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 41st Meeting held at the Novartis Foundation, 41 Portland Place, London, on Thursday 13th November 2008

Meeting Commenced at: 10:46

PRESENT

Dr Susan Barnes	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	**(RC)**	-	Advisory Committee on the Safety of Blood, Tissues and Organs SaBTO **(Observer)**
Dr Morag Ferguson	**(MF)**	-	National Institute for Biological Standards and Control
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 Stephen Inglis	**(SI)**	-	Director, National Institute for Biological Standards and Control
Dr Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
Mrs Linda Lodge	**(LL)**	-	Standing Advisory Committee on Information Technology
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Willie Murphy	**(WM)**	-	National Medical Director, Irish Blood Transfusion Service **(Observer)**
Dr Morris McClelland	**(MM)**	-	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 Lorna Williamson	**(LW)**	-	Medical Director, NHS Blood and Transplant
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology

Action

1. APOLOGIES

Dr Bruce Cuthbertson	**(BC)**	-	Representing the Quality Managers of the 4 UK Blood Services
Dr Rachel Green	**(RG)**	-	Standing Advisory Committee on Stem Cells
Prof. David Pegg	**(DP)**	-	Standing Advisory Committee on Tissues
Dr Chris Prowse	**(CP)**	-	Standing Advisory Committee on Blood Components

2. NEW SAC CHAIRS

4 new SAC chairs had been appointed since the last JPAC meeting in June:

- Dr Nay Win chair of the Standing Advisory Committee on Immunohaematology
- Dr Sue Barnes chair of the Standing Advisory Committee on Care and Selection of Donors
- Dr Rachel Green chair of the Standing Advisory Committee on Stem Cells
- Dr Chris Prowse chair of the Standing Advisory Committee on Blood Components

Action

SM welcomed SB to her first JPAC meeting and NW to his first meeting as Chair of the SACIH.

The announcement from Keith Thompson, Chief Executive of SNBTS and Chair of the UKBTS Forum, regarding SM's appointment as the Professional Director of JPAC had already been circulated to JPAC.

SM informed JPAC that she had formally taken up the position on 1st November 2008 – 13 days ago.

3. MINUTES OF THE MEETING 26TH JUNE 2008 – JPAC 08-64

The minutes were approved with one amendment to the action on item 5.3. which should be against SM for the UKBTS Forum report.

4. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 08-65

4.1. 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" – item 5.1.

Work is on going.

Post Meeting Note: Change Notification No. 1 2009 – Components suitable for use in intrauterine transfusion, neonates and infants under one year issued 20th January 2009.

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

This will be included in the JPAC report to the UK BTS Forum Meeting on 5th December 2008.

Post Meeting Note: This was submitted to the UKBTS Forum meeting on 5th December 2008 for information and action by the individual Blood Services.

4.3. Discussion Paper: Foreign travel, tropical areas and donor selection (JPAC 08-43) – item 5.3.

PEH has sent LW ideas on how to take this forward and outlined a plan of what she thinks needs to be done. PEH will send SB the details. **PEH**

SB will discuss with Crispin Wickenden [Head of Market Research & Analysis (NHSBT)] and put on the work plan for the SACCSD. **SB**

4.4. Human Parvovirus PARV4 – Risk Assessment – item 5.5

The risk assessment has been amended to include a comment made at the last JPAC meeting in June.

4.5. A proposal to remove endoscopy as a deferral criteria for tissue donors (v1) – item 6.1.

Re-examination of the evidence for risks from endoscopy for whole blood and

Action

other donors has been put on the SACTTI work plan.

4.6. Post-thaw stability of fresh frozen plasma – item 7.1

Studies are now underway on the properties of thawed fresh frozen plasma during extended periods of liquid storage.

4.7 Discard limits for blood components – item 7.3

This has been discussed with CP, new chair of SACBC, and SACBC will resubmit the proposal after further consideration. **CP**

5. STANDING ADVISORY COMMITTEE ON TISSUES

In the absence of DP SM presented the SACT papers, which had already been to the JPAC Executive.

5.1. Proposal to raise the donor age limit for pulmonary heart valves – JPAC 08-66

Pulmonary allografts are in much greater demand than aortic allografts due to their application in the Ross procedure, and to an increasing requirement for pulmonary patch grafts. This is reflected in the stock levels held in UK heart valve banks.

It is standard practice in non-blood service UK heart valve banks, and many other countries, to bank pulmonary valves from donors up to age of 65. Increasing the donor age limit to from 60 to 65 would result in a 31% increase in pulmonary valve donation.

JPAC endorsed the recommendation to increase the upper age limit for pulmonary valve donation from 60 to 65 years, whilst keeping the age limit for aortic valve donation at 60 years.

Action: DP to send CJS the appropriate text for a Change Notification.

Post Meeting Note: Change Notification sent to the Medical Directors for approval 26th February 2009.

5.2. Consideration for changes to the Red Book regarding testing of neonatal deceased tissue donors – JPAC 08-67

It is often not possible to obtain adequate blood samples from neonatal deceased tissue donors to comply with the current Red Book microbiological testing requirements that necessitate full microbiological testing of both the mother and the neonate.

JPAC endorsed the recommendation to change to the Red Book entry regarding the microbiological testing requirements for neonatal deceased tissue donors

Action: DP to send CJS the appropriate text for a Change Notification.

Post Meeting Note: Change Notification sent to the Medical Directors for approval 26th February 2009.

5.3. Proposal to remove the requirement for face-to-face interviews for living

Action

donors – JPAC 08-68

JPAC endorsed the recommendation that Section 22.3 of the Red Book should be amended by removing the sentence *"Information must be obtained by face-to-face interview with the donor."* and replacing it with the sentence *"Information may be obtained from the donor by either face-to-face interview or by recorded telephone interview by appropriately trained tissue bank staff."*

Action: DP to send CJS the appropriate text for a Change Notification.

Post Meeting Note: Change Notification sent to the Medical Directors for approval 26th February 2009.

There was extensive discussion of this paper during which several points were raised. It was agreed that when there are problems such as when English isn't the first language, or other reasons for suspecting that communication is not ideal, then there should be a face to face interview. It was also agreed that this should not be seen as a precedent that could apply to other screening procedures such as prior to blood donation.

5.4. Proposal to withdraw the "Consent to tissue donation" Position Statement – JPAC 08-90

This position statement was prepared in November 2003 and sets out the ethical and some practical requirements for consent to be valid. It does not deal with the 'opting out' systems that the Government is currently considering. Relevant legislation has changed drastically since 2003 and the Human Tissue Authority (HTA) has now issued comprehensive guidance in a "Code of Practice on Consent".

JPAC endorsed the withdrawal of the "Consent to Tissue Donation" Position Statement.

Action: CJS remove the position statement from the JPAC website.

Post Meeting Note: The position statement "Consent to tissue Donation" removed from the JPAC website 19th November 2008.

6. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

6.1. Answers to UK BTS Forum's questions to SACTTI concerning bacterial risks to platelet components and pathogen inactivation – JPAC 08-69

This issue had been discussed at the UK BTS Forum on 18th April 2008 (UK BTS Forum paper 08.26) and PEH, as Chair of SACTTI, was asked to consider a number of questions relating to the bacterial screening of platelet components. SACTTI asked its expert in Bacteriology, Dr Vanya Gant, to prepare a paper in response to these questions which was discussed at the SACTTI meeting on 2 September 2008.

After discussion it was agreed that the paper would be sent to the UK BTS Forum in December.

Action: Include in the JPAC report to the next UK BTS Forum Meeting.

Action

Post meeting note: This paper was submitted to the UKBTS Forum meeting on 5th December 2008.

6.2. Discussion paper on policies to reduce transfusion transmitted HBV – JPAC 08-70

The original paper had been submitted to JPAC in November 2006.
The response from the Advisory Group on Hepatitis to this paper was noted and it was agreed that JPAC should keep a watching brief.

It was also noted that this may be of interest to SaBTO as they have a model for cost effectiveness etc. RC confirmed that this issue is not on the SaBTO work plan.

MF reported that NIBSC has CE marked NIBSC working standards for HIV-1 DNA and HCV RNA in order to comply with the EU In vitro Diagnostic Medical Devices Directive. The NIBSC working standard for HBV DNA has not yet been CE marked. However, if the NBS implement NAT testing for HBV DNA and contract NIBSC to supply a batch of HBV DNA working standard, this will be CE marked.

6.3. Congo Crimean Haemorrhagic Fever (CCHF) Risk Assessment v2 – JPAC 08-71

This was discussed at length. JPAC endorsed the recommendation to take no specific action in the absence of any evidence of disease imported into the UK and that 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.

It was noted that the Irish BTS do defer for CCHF.

6.4. Simian Foamy Virus (SMF) Risk Assessment v2 – JPAC 08-72

The previous version of this risk assessment had been discussed extensively at the JPAC meeting in November 2006 (JPAC 06-52a and 06-52b).

JPAC endorse the SACTTI recommendation to take no action at this time but to keep the matter under review.

7. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

In the absence of CP SM presented the SACBC papers.

7.1. JPAC Position Statement – Granulocyte Therapy – JPAC 08-73

There was a lengthy discussion of this paper during which several points were raised.

The current position of the UK Blood Services is that we do not allow volunteer donors to be treated with GCSF / steroids to provide apheresis granulocytes, but it is recognised that some centres will collect from family and friends for this purpose. The alternative treatment of buffy coats means that patients may be exposed to up to 20 donors per day.

- It was agreed to seek further opinion from an ethical perspective, and IMF agreed to consult with the RCPath (they have an ethical committee). **IMF**

Action

- LW will find out about the ethical position with regard to living organ donors. **LW**
- SM to check the status of the pooled granulocyte study with Simon Stanworth. **SM**

JPAC endorsed the content of this position statement with the removal of the word "Arguably" from the first sentence of the first paragraph of the Summary.

Post Meeting Note: Updated Position Statement posted on the JPAC website on 20 January 2009.

7.2. Revised Factor VIII specification for Methylene Blue cryoprecipitate – JPAC 08-74

The Factor VIII specification for Methylene Blue (MB) plasma is lower than for standard FFP, whereas currently the same specification is used for MB cryoprecipitate and standard cryoprecipitate. This specification cannot be met consistently because of the lower Factor VIII content of the starting material.

This paper recommends a revised specification for MB cryoprecipitate that 75% of donations contain >50 IU factor VIII and >140mg fibrinogen per donation.

NG raised concerns, from the Regulators point of view, that if a reduction in the factor VIII specification for methylene blue treated cryo was agreed this was contra to the Blood Safety and Quality Regulations (BSQR) and the EU Directive. After lengthy discussion it was agreed that SM should formally write to NG.

Post Meeting Note: SM wrote to NG on 1st December 2008. Reply received from NG on 16th December – MHRA approved this as a "new" component as per the provision in Directive 2004/33/EC Annex V Table 1(5).
Change Notification No. 3 2009 – Revised Factor VIII specification for Methylene Blue-treated cryoprecipitate issued on 6th February 2009.

7.3. X-ray irradiation of blood components – paper 5 – update of previous version – JPAC 08-75

This paper is a combination and update of several SACBC papers on X-ray irradiation of blood components submitted to JPAC in 2007 and 2008, and includes new NHSBT laboratory data on red cell components for exchange transfusion and intra-uterine transfusion.

JPAC endorsed the recommendation that X-irradiation can be used as an alternative to gamma irradiation for red cells, platelets and granulocytes.

Post Meeting Note: Change Notification No. 6 2009 - X-irradiation as an alternative to γ-irradiation issued 10th February 2009.

7.4. Clarification on storage temperature for high glycerol frozen red cells – JPAC 08-76

JPAC endorsed the recommendation that Council of Europe phrasing replace the current one in section 8.8 of the "Red Book" and that a Change Notification should be issued.

The Council of Europe("14th Edition Guide to …") page 142, specifies:

"Storage and stability

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Red cells in frozen state

These should be constantly maintained at:

- –60°C to –80°C if stored in an electrical freezer when a high glycerol method is used
- –140°C to –150°C if stored in vapour phase liquid nitrogen, when a low glycerol method is used

The storage may extend to at least ten years if the correct storage temperature is guaranteed"

Action: CP to send CJS the appropriate text for a Change Notification.

Post Meeting Note: Change Notification No. 4 2009 – Clarification on storage temperature for high glycerol frozen red cells issued 10th February 2009.

7.5. Proposed change to Red Book label specification – JPAC 08-77

JPAC endorsed the change in wording to Chapters 25 and 28 of the "Red Book".

Action: CP to send CJS the appropriate text for a Change Notification.

Post Meeting Note: Change Notification No.5 2009 – To clarify label dimensions and requirements to assess label glue in the Red Book issued 10th February 2009.

7.6. Summary on overnight hold processing – JPAC 08-78

This paper was circulated for information and is a summary of progress within NHSBT.

RC is going to check on validation data on plasma produced following overnight hold.

Action: RC **RC**

7.7. Remanufacture of exchange transfusion units to SAGM red cells after 6 days storage – JPAC 08-79

JPAC endorsed the recommendation that the data in this study supports the remanufacture of exchange transfusion red cell units to SAGM additive red cells, up to 6 days after donation, with an overall shelf life of 42 days at 4°C.

Post Meeting Note: Change Notification No.7 2009 – Remanufacture of exchange transfusion units to SAGM red cells after 6 day storage issued 10th February 2009.

8. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

8.1. Recommendation for removal of the upper age limit for re-attending whole blood and component donors- Final version – JPAC 08-80

SB highlighted the changes made to this paper after comments had been received following its submission to the JPAC meeting on 26th June.

Action

NG raised an issue with the quality of components from older donors. SB reported that the USA have been accepting older donors for 20 years and have not reported any problems.

It was agreed that this paper can be posted on the JPAC website www.transfusionguidelines.org.uk in the "Document Library". This area of the website is available to the general public.

Post Meeting Note: Posted on the JPAC website November 2008.

9. STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE

9.1. Storage of thawed FFP – User consultation – JPAC 08-81

At the JPAC meeting on 26th June (JPAC 08-47) DN was asked to carry out *"... further consultation with users ... to identify clinical indications and demand*" for an extended life thawed FFP component.

A limited survey amongst blood banks was presented which suggested that they would welcome extended life, but no trauma surgeons have yet been consulted.

RC is planning further work on extended life FFP and will subsequently prepare a report for JPAC. **RC**

It was noted that there may be a need for clinical trial data.

10. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

10.1 UK ISBT 128 Implementation Consideration – JPAC 08-82

This was raised at the UK BTS Forum meeting in September 2008.

SM had asked LL to submit a paper to JPAC highlighting the issues surrounding the implementation of ISBT 128.

Action: Include in the JPAC report to the next UK BTS Forum.

Post Meeting Note: This paper was submitted to the UKBTS Forum on 5th December 2008.

10.2. Portfolio of Blood Components for use by the 4 UK Blood Services: update – JPAC 08-83

LL gave an update on the progress on development:

- 1st iteration is complete and has been reviewed. Updates are being developed.
- 2nd iteration is ready for review.
- 4 iterations are anticipated prior to version 1 being ready December 2008.

11. UKBTS FORUM

SM highlighted points from the UK BTS Forum minutes from 5th September

Action

which concerned JPAC.

12. ANY OTHER BUSINESS

12.1. Change in Department of Health Blood Policy Lead - JPAC 08-84

Circulated for information.

12.2. JPAC Declaration of Interests Form - JPAC 08-85

JPAC approved the new form. It was agreed that the form should be completed annually and returned to the JPAC Manager. SAC Chairs would continue to ask for "Declarations of interest" at the beginning of each meeting. New members would be asked for declarations covering the last three years.

Action: CJS to circulate the new form to all committee members, via the SAC Chairs.

Post Meeting Note: Declaration of Interests form circulated 31st December 2008.

12.3. UK Blood Services submission to European Directive: West Nile Virus donor deferral (Annex III section 2.2.1) – update - JPAC 08-86

At the request of Brian McClelland NG had emailed Thomas Bregeon with a proposal from the UK regarding donor deferral for West Nile Virus. NG had not received a reply to his email and no information had been received regarding the 2008 meeting of the Blood Competent Authorities.

Post Meeting Note: Email received from Thomas Bregeon 14th November 2008.

"... The recent occurrences in Italy, Hungary and Romania have shown that there is a need for an improved surveillance system of the disease, especially in the context of blood transfusion, as the cases are likely to be more frequent in the future. So we are working now on an optimisation and "protocolisation" of the quick alert system , as well as thinking how the Directive should be interpreted when countries - e.g. Italy today - implement NAT testing in parallel to deferrals. Hence we plan to dedicate a big slot of the next meeting of the Blood CA (which will be the last week of January by the way - at last we could find a suitable room for it...) on this precise topic. Your suggestions could be discussed in this context. ..."

12.4 SaBTO

It was agreed that "SaBTO" would appear as a standing item on all future JPAC meeting agendas.

LW reported that the public meeting on vCJD had gone extremely well and that the plan is have an open meeting on a relevant topic every year.

The closed meeting mainly dealt with issues around tissues. SaBTO are minded to recommend that there should be informed consent for blood transfusion, and have asked for a paper to be presented to their next meeting in January 2009 detailing how this might be achieved and any implications for implementation. Catherine Howell, a member of SaBTO is leading the production of this paper.

- SaBTO have asked for further information (to be presented in April 2009) on the feasibility of 4 further measures to reduce the risk of vCJD transmission

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by blood. These are:

1) extending the importation of FFP to all recipients (DH is leading on this paper)
2) Increasing the percentage of platelets collected by apheresis to 100% (NHSBT has already committed to reaching 80% by March 2009)
3) Importation of red cells for children
4) Using double dose red cells in children or young adults for people who need 2 units or more on a regular basis.

A paper on further measures to reduce the risk of bacterial contamination of platelets, which includes pathogen inactivation, is due to be considered at their meeting in January 2009.

12.5. Morag Ferguson

Morag is retiring from NIBSC in 2009 and this was her last JPAC meeting. SM thanked Morag on behalf of JPAC for her contribution to the committee for more than 10 years.

The meeting concluded at 14:45

13. DATES AND VENUES OF FUTURE JPAC MEETINGS

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