APPROVED 09/07/2009

# Joint UKBTS/NIBSC Professional Advisory Committee

## Minutes of the 42nd meeting held at the Association of Anaesthetists, 21 Portland Place, London, on Thursday 12th March 2009

**Meeting Commenced at: 10:45**

**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) |
| 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 |
| Prof. David Pegg | **(DP)** | - | Standing Advisory Committee on Tissues |
| Dr Chris Prowse | **(CP)** | - | Standing Advisory Committee on Blood Components |
| 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 |

SM welcomed CP to his first JPAC meeting as Chair of the SACBC.

**Action**

**1. APOLOGIES**

| | | | |
|---|---|---|---|
| Prof. Ian Franklin | **(IMF)** | - | Medical Director, Scottish National Blood Transfusion Service |
| Dr Rachel Green | **(RG)** | - | Standing Advisory Committee on Stem Cells |
| Dr Morris McClelland | **(MM)** | - | Medical Director, Northern Ireland Blood Transfusion Service |
| Dr Bruce Cuthbertson | **(BC)** | - | Representing the Quality Managers of the 4 UK Blood Services |
| Dr Derek Norfolk | **(DN)** | - | Standing Advisory Committee on Clinical Transfusion Medicine |

**2. MINUTES OF THE LAST MEETING HELD ON 13TH NOVEMBER 2008**

The minutes were approved as a true record of the meeting with two minor typo amendments.

**3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 09-03**

**Action**

**3.1 Discussion Paper: Foreign travel, tropical areas and donor selection – item 4.3**

SB is taking this forward and has spoken with Andy Young (Director of Blood Donation NHSBT) and Crispin Wickenden (Head of Market Research & Analysis NHSBT). A telephone survey, using the NCC, may be the best way to get the information and SB is awaiting the relevant costings. It is proposed that this would be funded by JPAC.

SM asked SB to prepare a short paper for the next UKBTS Forum.

*Post Meeting Note: Paper submitted to the UKBTS Forum meeting on 12th June 2009.*

**3.2 Discard limits for blood components – item 4.7**

CP reported that this will discussed at the SACBC meeting in June. JPAC agreed this could be removed from the action list.

**3.3 JPAC Position Statement – Granulocyte Therapy (JPAC 08-73) – item 7.1.**

SM is awaiting further information from IMF on the ethical perspective.

LW agreed to contact IMF and together they would write a brief paper on the ethical position with regard to living organ donors. **IMF & LW**

The clinical study on the new pooled granulocyte component is progressing. SM confirmed that JPAC will wait until the end of the study for the report rather than review an interim analysis as it is estimated that recruitment is approximately 2/3 complete (22 patients out of 30).

**3.4 Summary on overnight hold processing (JPAC 08-78) – item 7.6**

This paper had been circulated for information at the November 2008 meeting and is a summary of progress within NHSBT. RC had been asked to check on data on cytokine levels in plasma produced following overnight hold, but commented that there is very little comparative data with <8 hour hold. However studies examining plasma from ambient storage of whole blood for 24 hours do not show levels that are elevated compared with reference ranges.

**3.5 Storage of thawed FFP – User consultation (JPAC 08-81) – item 9.1**

RC is planning further work on extended life FFP. A proposal will go to SACBC and then come back to JPAC. It is estimated that the validation will be completed by the end of the year as this is not a high priority.

## 4. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

**4.1 Babesia risk assessment v1 - JPAC 09-04**

PEH went through this risk assessment for JPAC. The recommendation that no specific action is required by the UK Blood Services with regard to Babesiosis was endorsed.

**Action**

**4.2 Chikungunya virus risk assessment v2 - JPAC 09-05**

PEH reported that this risk assessment has been updated to reflected information which has become available since 2006.

The recommendation to maintain current advice with respect to deferral of donors who have visited areas where there is current Chikungunya activity was endorsed.

The number of references listed under section 6 was noted and JPAC agreed that a list of references should appear on all future risk assessments. **Action:** PEH **PEH**

It was queried whether we have a threshold on numbers with regard to an outbreak. It was agreed that this would depend not only on numbers but on location and perceived risk and that individual assessment is required.

**4.3 Chikungunya virus infection: Ravenna region of Italy - JPAC 09-06**

There have been no further cases of Chikungunya virus infection in northern Italy in 2008 therefore SACTTI recommendation is to remove the deferral of donors who have recently returned from the Ravenna region of northern Italy, with immediate effect. This was endorsed by JPAC.

CJS will issue a Change Notification using the text provided in JPAC 09-06.

*Post meeting Note: Change Notification issued on 1st April 2009.*

**4.4 JPAC Position Statement on Creutzfeldt-Jakob Disease - JPAC 09-25**

JPAC endorsed the revised position statement, with a couple of minor amendments and agreed to its publication on the JPAC website.

Action: PEH to amend the position statement and send to CJS.

*Post Meeting Note: Updated Position Statement posted on JPAC website 4 June 2009*

PEH asked if statistics were available with regard to the number of hits/ downloads of position statements on the JPAC website. CJS informed JPAC that this information could be provided. Action: CJS to send relevant statistics to PEH

*Post Meeting Note: Website statistics for the Position Statement on CJD:*
*01 Feb 09 to 29 Apr 09 = 303*
*01 Apr 08 to 29 Apr 09 = 1,486*

**4.5 Dengue risk assessment v2 - JPAC 09-07**

JPAC endorse the recommendation that no change is required in donor selection criteria with regard to travel to dengue-affected countries. The UK Blood Services should continue to keep a watching brief with regard to the number of imported cases of infection in the UK and consider travel-dependent deferral only if the situation changes to indicate that there is an increased risk to the blood supply and the effect of any additional travel-dependent donor deferral is more fully understood.

**Action**

**4.6 Leishmaniasis risk assessment v1 - JPAC 09-08**

It was noted that Section 1 doesn't contain information regarding the pathogenicity/incubation period etc. and asked that Prof Chiodini include this in the risk assessment.

With the above mentioned change JPAC endorsed the risk assessment and the recommendation that no specific action is required by the UK Blood Services with respect to Leishmaniasis.

**Action:** PEH to ask Prof Chiodini to update the risk assessment. **PEH**

PEH informed JPAC that, in the USA, troops returning from Iraq are deferred because of the risk of Leishmaniasis. This is unnecessary, as the risk is of cutaneous Leishmaniasis, which is not relevant to blood transfusion.

**4.7 Toxoplasmosis risk assessment v1 - JPAC 09-09**

Prof Peter Chiodini, Dr Ed Guy, Dr Rick Holliman and Dr Darrell Ho-Yen had a special meeting in London and produced this risk assessment for SACTTI.

PEH informed the group that further information is awaited on heart valves/hearts in the table on page 11 "Organ Transplants". **PEH**

It was also noted that Section 1 does not contain information regarding pathogenicity etc. **PEH**

With these amendments to the risk assessment JPAC endorsed the recommendation that no specific measures are required by the UK Blood Services with respect to Toxoplasmosis.

**4.8 Non-pandemic influenza A risk assessment v2 - JPAC 09-10**

JPAC endorsed the recommendation that no specific measures are required with respect to blood safety and non-pandemic Influenza A. The issues raised by non-pandemic Influenza A are likely to be those of sufficiency of supply.

**4.9 H5N1 pandemic influenza risk assessment v2 - JPAC 09-11**

JPAC endorse the recommendation to keep the matter under review as/when further information becomes available. There was some discussion about potential collection of specific Ig from donors in the event of an epidemic. It was agreed to forward the risk assessment to the UK Emergency Planning Group via Richard Rackham. **Action**: SM **SM**

**4.10 Estimates of the frequency (or risk) of HBV, HCV, HIV and HTLV (type I) potentially infectious donations entering the UK blood supply, 2002 – 2007 - JPAC 09-12**

The estimates of frequency of risk for transmission of infection through UK blood donations are updated yearly and these figures include data for 2007. With the exception of HTLV risk, which is stable, all other risks are decreasing.

These estimates had been discussed at the JPAC EWG meeting in January and it was suggested that as there is a downward trend Table 1 should also be

**Action**

published along with summary.

Concerns were raised about the error frequency, which has also been queried at SACTTI and JPAC Executive Working Group. CP commented that there is a model for error rates on the assay on CMV – he will send information to PEH. It was also noted that Matt Jansen and Cees van der Poel were working on models in this area. **CP/PEH**

JPAC agreed that the Summary and Table 1 should be published with a proviso that it will be updated, PEH estimated by mid-year.

### 4.11 SACTTI Working Party on Bacteria - JPAC 09-13

The formation of a SACTTI Working Party on Bacteria had been approved at the UK BTS Forum on 26th February and was endorsed by JPAC.

The aims are:

1. Advise on standards for blood/ component donation, including skin preparation prior to venepuncture and prevention of cross-contamination from staff or equipment.
2. Advise on optimal methods for bacterial screening of platelet components prior to release / transfusion
3. Advise on the efficacy of currently available Pathogen Inactivation systems for reducing the risk of bacterial contamination in platelet components.

This Working Party will be Chaired by Dr Ty Pitt, who is also a member of SaBTO.

SM & PEH will discuss timelines or prioritisation of these issues (2 and 3 are main priority in next 6 months).

## 5. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

### 5.1 DEHP blood bag symbol v1 - JPAC 09-14

Incoming legislation (driven by the Medical Devices Directive) means that blood bag manufacturers will have to have introduced the symbol by 31st March 2010 at the latest.

JPAC agreed that there should be one entry in a general section of the Blood Components Portfolio. Concerns were raised over the size and location of the symbol.

**Action:** CP will take this forward with LL and keep JPAC informed. **CP & LL**

It was also agreed that Catherine Howell should be made aware of this change. Consideration will have to be given as to what and how this needs to be communicated to hospitals.

**Action:** SM will liaise with Catherine Howell and Derek Norfolk. **SM**

### 5.2 Minimal Performance Criteria for CE marking of selected Medical Devices: A Discussion Document - JPAC 09-15

**Action**

This paper, after a few minor amendments, was approved at the UK BTS Forum meeting in February 2009.

After a long discussion it was agreed that CP and LW will formally write to NG regarding this issue and he would forward the information on to the appropriate people at the MHRA who deal with medical devices to request a meeting. **CP & LW**

### 5.3 Feedback from the SACBC meeting on 28th January 2009

CP informed JPAC that there are a number of products requiring specification and sign off by MHRA.

- Intercept treated platelets in additive and plasma
- Additive (& saline) washed platelets – platelet content >=200*$10^9$ per adult dose
- Additive washed AP215 washed red cells – specification and shelf life (14d)
- Upper pH limit for platelets to be removed (See Dumont et al BEST study, "-218 & C-036)
- Prion filtered red cells

SM requested that in the first instance these should come to the JPAC Executive Working Group meeting on 14th May 2009. **Action:** CP **CP**

## 6. SaBTO

As LW had to leave the meeting early this item was brought forward on the agenda.

RC informed JPAC that the following items were due to be discussed at the next 2 SaBTO meetings.

**April 2009**

- Double dose red cells
- Importation of red cells for children
- Prion filtration of red cells
- Update on vCJD testing
- Update on Informed consent
- Updated MSBTO Guidance on Safety of Tissues

**July 2009**

- Importation of FFP/Cryo and alternatives to cryo
- 100% apheresis platelets
- risk reduction for bacterial contamination of platelets
- review of donor deferral

The main topics discussed at SaBTO's January meeting were:

1. Consent for blood transfusion

   SaBTO are keen that there is informed consent for transfusion across the UK and had tasked Catherine Howell with taking this forward, who gave a presentation at the January meeting. SaBTO were not content that there was inconsistent practice around the UK and have asked the group led by Catherine Howell to do a wide consultation on this issue.

**Action**

2. vCJD

An overview was presented by Hester Ward on the possible case of vCJD in a patient of MV genotype reported in the media recently. It was noted that this case, even if confirmed, does not alter risk assessments carried out by DH on vCJD since these have always assumed that all genotypes are susceptible to infection. There was an update on studies from the HPA on efficacy of prion removal. Western Blot data is now available on both 263K and 301V rodent models using exogenous spike, bioassay data is expected in April 2009 for the 263K model and January 2010 for the BSE model. Clinical studies are ongoing in the UK in terms of safety. SaBTO determined that it was premature to make a recommendation to implement prion filtration at that meeting, but recommended that UK Blood Services should be prepared in case such a recommendation is made. The Secretariat are going to ask one of the Royal Colleges (paediatrics) about the ethics of implementing any safety measures for selected patient groups rather than all recipients. The SaBTO secretariat are also asking the BCSH for an opinion on whether paediatric haematologists would be happy to use filtered red cells in children based on data from safety studies in adults. At the April meeting there will be more data on prion filtration from the HPA and from the clinical studies and SaBTO will receive an update on this.

3. Bacterial screening / pathogen inactivation of platelets

SaBTO had some initial discussions on this topic. SaBTO is not content that UK Blood Services have different approaches. SaBTO have tasked a sub-group led by Ian Franklin to consider this issue in more depth and come back to the committee in July with some recommendations.

The UK BTS Forum cannot formally make recommendations to SaBTO, but it was agreed that LW will write to the Chair of SaBTO expressing opinions of the UK BTS on the options currently under consideration by SaBTO.

## 7. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

### 7.1 Recommendations on apheresis donation in young and first time donors (Final version 2.3) - JPAC 09-16

JPAC endorsed the following recommendations and the removal of the current prohibition on component donation in first time donors and donors under 18 years of age. This will bring the acceptance criteria into line with those for whole blood donation.

Recommendations

a) Donors of blood components by apheresis can safely start to donate from their 17th birthday, provided that they meet UK Blood Services' donor acceptance criteria as assessed by routine procedures. (Level B recommendation)

b) Donors may safely donate apheresis components without a prior whole blood donation. (Level B recommendation) However apheresis platelet donors should have a full set of mandatory infection screens performed at least 8 weeks prior to the first donation.

**Action**

Action: SB to send the appropriate text to CJS so that a Change Notification can be issued. This paper would be referenced in the Change Notification and published on the JPAC website.

*Post Meeting Note: Change Notification issued 19th May 2009.*

**7.2 Responsibility for blood collection - Revised wording to Red Book - JPAC 09-17**

After discussion on the exact wording JPAC endorse the recommendation to change the wording in the Guidelines for the Blood Transfusion Services in the United Kingdom 7th Edition, Chapter 4, Section 4.2, 1st paragraph as follows:

"The ultimate responsibility for the correct safe procedure for the collection of blood rests with the designated medical or biomedical scientist responsible for the blood establishment, this would normally be delegated to a medical consultant; the advocacy and guardianship of high quality care for donors is the responsibility of the designated clinical lead in attendance and that must be a registered nurse or medical practitioner."

Action: SB to send the appropriate text to CJS so that a Change Notification can be issued.

*Post Meeting Note: The text for the Change Notification was revised after the JPAC meeting and the following was approved by the Medical Directors on 18-05-09 and Change Notification No. 13 issued on 19th May 2009.*

*"The ultimate responsibility for ensuring that every unit of blood and blood components has been collected in accordance with the Blood Safety and Quality Regulations (2005) rests with the "Responsible Person" for the Blood Establishment. The advocacy and guardianship of high quality care for donors is the responsibility of the designated clinical lead in attendance and that must be a registered nurse or medical practitioner."*

**7.3 Revision of the Donor Selection Guidelines**

SB informed JPAC that the SAC CSD are working hard on a complete revision of the DSG, especially the index.
Action: SB will bring to the next JPAC meeting on 9th July.

*Post Meeting Note from SB: Following the sad death of Dr Serge Six there has been a delay in this work which is now starting to get back on track and hopefully will be available for approval at the next meeting. Action: SB* **SB**

SAC CSD are also looking at how to bring the Geographic Disease Risk Index (GDRI) up to date.

**8. STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE**

**8.1. Handbook of Transfusion Medicine – New 5th Edition – JPAC 0918**

In the absence of DN CJS updated JPAC on the position of the next edition of the Handbook of Transfusion Medicine.

**Action**

A first meeting has been held with TSO (publishers) and it is hoped that this edition will be published end of 2009/beginning of 2010.

Several ideas were discussed and it was decided that this edition would be published as a hardcopy, on the JPAC website and that a PDA version (eBook) would also be available to download from the JPAC website.

In the first instance the content\format of the new edition will be reviewed by members of the SAC CTM:

Shubha Allard
Edwin Massey
Helen New
Derek Norfolk
Caroline Smith

and an action plan established.

SM requested that the text would come to JPAC. **Action:** DN and CJS — **DN & CJS**

## 9. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

### 9.1 Proposed change: Red Book Chapter 13.10 Mandatory testing of blood donations - JPAC 09-19

JPAC approved the following change to Section 13.10.7 Antibody screen for blood for neonates (page 180):

".....performed using a two cell panel expressing the following antigens as a minimum: C;c ;D;E;e;K;k;$Fy^a$;$Fy^b$;$Jk^a$;$Jk^b$;S;s and M''

Action: NW to send the appropriate text to CJS so that a Change Notification can be issued.

*Post Meeting Note: Change Notification No 16 Mandatory testing of blood donations sent to the Medical Directors for approval 24-06-09.*

## 10. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

### 10.1 Electronic web based UK Products Portfolio - JPAC 09-20

LL informed JPAC that SACBC have highlighted and signed off changes to electronic portfolio based on demo given on 28th January.

Final adjustments to data content being made ready for Quality and BC (SNBTS QA) has had a system demonstration. LL has emailed BC to ask if this has been disseminated to the other UK Quality Managers.

To implement this electronic portfolio for wider use, the UKBTS Forum will need to fund a hosting site for the product, as the JPAC website is not set up to host production databases. At present the portfolio is on the SNBTS server.

The next step is for the system to be validated and SACBC and SACIT have been given access. Subsequently a piece of work needs to be planned that determines how this system will be rolled out for use by the wider transfusion community. It

**Action**

will require a planned implementation that incorporates the introduction of the new format blood component label structures. LL recommended that this is initiated as a UK wide project.

**Action:** SM to discuss future plans with LL. **SM & LL**

**10.2 Remit for Project Manager for ISBT 128 - JPAC 09-21**

JPAC agreed that expressions of interest for this post should be sought from the 4 UK Blood Services, with a 3 month time scale. It was agreed that this should go through the Chief Executives.

**Action:** LL to send text to CJS and LW to send to the Chief Executives. **LL & LW**

## 11. STANDING ADVISORY COMMITTEE ON TISSUES

**11.1 Human Tissues Authority – licence fees**

DP wanted to appraise JPAC of the large rise in the licensing fees proposed by the HTA. The closing date for consultation was 5th March and the increase in fees will start from 1st April 2009.

It is estimated that the proposed changes will increase licensing costs by a factor not less than x 5 which will have a major effect on total costs to hospitals. There are concerns on the effect this might have on the use of tissues and increase in importation of tissues.

SM asked DP to keep JPAC informed of developments. **Action:** DP **DP**

## 12. JPAC WEBSITE TRANSFUSIONGUIDELINES.ORG.UK

**12.1 Posting JPAC supporting papers on the JPAC website - JPAC 09-22**

JPAC supported the new area created in the Document Library of the JPAC website for JPAC background papers.

## 13. UKBTS FORUM

**13.1 Report back from the UKBTS Forum meetings on 5th December 2008 and 26th & 27th February 2009 – JPAC 09-23**

SM highlighted in this paper feedback relevant to JPAC.

JPAC Review

SM is in the process of putting together a specification for consultancy contract tender for the JPAC Review and will report back to the next JPAC meeting on 9th July. Several JPAC members as stakeholders (MHRA, NIBSC etc.) will be contacted during the review. **SM**

## 14. EUROPE: REPORTS FROM PA/PH/GTS AND CD-P-TS

**Action**

**14.1 Council of Europe "Guide to the preparation, use and quality assurance of blood components" - 15th Edition**

SM updated JPAC on the progress of the next edition of the CoE Guide. A small drafting group met in Strasbourg to work on the 15th edition. There are very few changes in content from the 14th edition, but the 15th edition will be split into two sections "Standards" and "Principles". The intention is that the "Standards" section will become the technical appendix of the Directives.

There is going to be a wide consultation period in the summer, before it is ratified in November.

New content will be considered for the 16th edition, and work will commence on this in September 2009.

**14.2 EDQM Symposium on optimal clinical use of blood components – JPAC 09-24**

As Chair of JPAC, UK Representative on the CD-P-TS, SM had received an invitation for 4 UK representatives to attend the EDQM Symposium on optimal clinical use of blood components. This was discussed and agreed at the UKBTS Forum in February.

As well as SM, Gerry Dolan from Nottingham University Hospital, Tim Walsh from The Royal Infirmary of Edinburgh and Brian McClelland will be attending.

**15. ANY OTHER BUSINESS**

**15.1 Proposed JPAC meeting dates for 2010:**

- Thursday 11th March
- Thursday 8th July
- Thursday 11th November

The proposed meeting dates for 2010 were agreed.

**The meeting concluded at 14:53**

**16. DATES AND VENUES OF FUTURE JPAC MEETINGS**

**2009**

- 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