

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 34th Meeting held at the West End Donor Centre, London, on Wednesday 1st March 2006

Meeting commenced at 10:45 am

PRESENT

Dr Bruce Cuthbertson	(BC)	- Standing Advisory Committee on Plasma for Fractionation
Dr Morag Ferguson	(MF)	- National Institute for Biological Standards and Control
Dr George Galea	(GG)	- Standing Advisory Committee on Tissues
Dr David Hutton	(DH)	- Standing Advisory Committee on Care and Selection of Donors
Dr Stephen Inglis	(SI)	- Director, National Institute for Biological Standards and Control
Dr Richard Jones	(RJ)	- Medical Director, Welsh Blood Service
Dr Liz Love	(LL)	- Standing Advisory Committee on Transfusion Transmitted Infections
Dr Sheila MacLennan	(SM)	- Standing Advisory Committee on Blood Components
Dr Brian McClelland	(BMc)	- Professional Director of JPAC (Chair)
Dr Morris McClelland	(MM)	- Medical Director, Northern Ireland Blood Transfusion Service
Ms Barbara Morris	(BM)	- Medicines and Healthcare Products Regulatory Agency
Dr Willie Murphy	(WM)	- National Medical Director, Irish Blood Transfusion Service
Dr Derek Norfolk	(DN)	- Standing Advisory Committee on Clinical Transfusion Medicine
Mr Stuart Penny	(SP)	- Standing Advisory Committee on Information Technology
Dr Derwood Pamphilon	(DP)	- Standing Advisory Committee on Stem Cells
Dr Tim Wallington	(TW)	- National Blood Service (Deputising for Dr Angela Robinson)
Miss Caroline J Smith	(CJS)	- JPAC Manager and minute taker

Action

1. APOLOGIES

Prof. Ian Franklin	(IF)	- Medical Director, Scottish National Blood Transfusion Service
Dr Angela Robinson	(AER)	- Medical Director, National Blood Service
Mr Chris Rudge	(CR)	- Medical Director, UK Transplant
Prof. Stan Urbaniak	(SU)	- Standing Advisory Committee on Immunohaematology

2. MINUTES OF THE MEETING ON 26th OCTOBER 2005

Minutes of the last meeting were approved.

3. MATTERS ARISING NOT ON THE AGENDA (Review of actions list) JPAC 06-01

3.1. Framework for evaluation of pathogen reduction of blood components – item 3.2.

It was agreed by JPAC that this very complex issue and will be taken off the JPAC agenda for the time being. BMC and LL will discuss what work has been done outside the meeting.

3.2. Transfusion Transmissible infectious agents: basis for a policy framework (JPAC

	<u>Action</u>
<u>05/37) – item 3.6.</u>	
Manuscript to be prepared for publication by BMc. The SACTTI Chair indicated that this framework is being piloted by SACTTI to structure its work.	BMc
3.3. <u>Recommendations for Revision of Microbiology Testing Requirements for Tissue and Stem Cell Donors – item 3.7.</u>	
GG and DP will work together to produce a revised/new chapter for the Red Book that will contain all the changes identified in paper Joint UKBTS/NIBSC Professional Advisory Committee: Recommendations for revision of microbiology testing requirements for tissue and stem cell donors (JPAC 05/35 – amended 23-06-05) that has been approved by MSBTO. This chapter should also include relevant changes in relation to stem cells.	GG & DP
<i>Note for information: MSBTO is working on 2 relevant topics: Production of new or revised MSBTO guidance on microbiology safety of tissues and organs and secondly specific technical standards for microbiological safety testing of organs for transplantation</i>	
Action: JPAC to work with MSBTO secretariat to pull this together.	BMc & CJS
3.4. <u>Leishmaniasis - SACTTI Working Party on Parasitology and Blood Safety – draft minutes of the meeting on 12th May 2005 – JPAC 05/46 – item 3.8.</u>	
SACTTI Recommendation: The words “tissues or blood” should be added to the relevant Donor Selection Guideline. Otherwise no change required.	
Action: SACCS	DH
3.5. <u>European Union Directive on Tissues and Cells 2004/23/EC update on implementation – item 6.2.</u>	
This Directive is due to come into force in April 2006. Implementation dates for the annexes are likely to be 7 th November 2006 for Annex 1 and Autumn 2007 for Annex 2.	
Actions noted in minute 3.3. are intended to ensure that the new tissue chapters for the Red Book fully reflect the requirement of 2004/23/EC Annexes 1 and 2	
3.6. <u>Granulocytes – item 9.1.</u>	
A further report and proposals is required – SACBC and JPAC. This was deferred until the June JPAC meeting.	SM & BMc
3.7. <u>Cryoprecipitate pooled, leucocyte depleted – item 9.2.</u>	
SACBC had reported on the need for an additional statement within the product specification that takes account of the fact that pooled cryo might occasionally be subjected to an additional freeze thaw step before use. Advice from SACBC was that there are 2 methods of manufacture and as both methods meet the specification an additional statement was not necessary.	
3.8. <u>Platelets suspended in plasma/additive solution – item 9.3.</u>	
SM informed JPAC that SACBC were amending these specifications. JPAC agreed that as the amendments were minor the specifications did not need to come back to JPAC. SM to update the specifications and send to CJS to issue a Change Notification.	SM

Action3.9. **Statistical basis of sampling for quality assessment – item 9.3.**

At the last JPAC meeting the issue of statistical basis of sampling for quality assessment was again discussed. Advice had been sought from the Quality Managers of the 4 UK Blood Services on finding appropriate people to help with an exercise to develop advice for JPAC.

SM had agreed, at the JPAC Executive Working Group meeting on 8th February, to lead this initiative and set up a task based team.

3.10. **Council of Europe specification for FFP – item 9.4.**

SM had requested the data on which SP-GS had based its recommendation to extend the shelf life of FFP from 24 to 36 months (at -30°C or below).

CJS had supplied the following papers; (1) Stability of Fresh Frozen Plasma: Results of 36 Month Storage at -20°C, -25°C, -30°C and -40°C and (2) Long-term Storage of Fresh Frozen Plasma at -40°C. A Multicenter Study on Stability of Labile Coagulation Factors over a Period of 3 Years, on which the recommendation had been based. These publications had been sent to SM

Action: SACBC – Is a change required to the Red Book on the specification of storage conditions of FFP?

SM**4. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**4.1. **Controls for high titre Anti-A/B testing of donations – JPAC 06-02**

Paper JPAC 06-02 prepared by SACIH was received discussed. JPAC noted that a further trial of one of the controls was in hand and that the estimated date for the availability of the product is May 2006. In discussion a question was raised about the clinical significance of IgG vs IgM anti-A and Anti-B, and the relevance if any of this to the composition of the standard.

Actions: (1) BMC will refer this question to SACIH and confirm the release date.
(2) BC will inform the Quality Managers of the 4 UK Blood Services.
(3) Information will be posted on the web site when available.

**BMc
BC
CJS****5. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY**5.1. **Purpose, strategy and objectives for the SACIT to March 2007 – JPAC 06-03**

BMc welcomed SP to his first JPAC meeting as Chair of the SACIT and Derek Norfolk to his first meeting as Chair of the SAC on Clinical Transfusion Medicine.

Paper JPAC 06-03 “Purpose, strategy and objectives for the Standing Advisory Committee on IT (SACIT) to March 2007” was presented and discussed.

JPAC endorsed proposed purpose, strategy, objectives and terms of reference. On the basis of this paper, SACIT will develop a workplan for 2006/2007.

In discussion a number of points were identified which will be taken into account in the development of the workplan.

1. Responsibilities for IT aspects of tissues and stem cells – data sets, labelling standards etc. It was noted that Mr Stefan Poniatowski (National Tissue Bank Manager NBS) had been recruited to SACIT to provide expertise relevant to

Action

tissues.

2. It was also pointed out that there is now an EU commission working group on nomenclatural labelling and IT standards for tissues. Dr Murphy undertook to provide the information about the UK member of this group. It was also noted that an international standard for barcode labelling of stem cell products has been developed by ICCBBA.

WM

The MHRA member drew the attention of JPAC to the requirements for IT systems to comply with current GMP and noted that the current version of the "Orange Guide" is available only on the Eudralex website (European Commission maintained website) – the printed version is not up to date. It was agreed that the JPAC Manager to inform Quality Managers group of this fact.

Post Meeting note: Information e-mailed to the Quality Managers of the 4 UK Blood Services on 13th April 2006.

5.2. **Commonality in blood component labelling and barcoding**

The Chair of the UKBTS Forum reported that they fully endorsed the moves to achieve commonality across the UK Blood Services.

It was noted that there is a need for formal approval by the MHRA, and the Departments of Health, of the proposed common UK blood component label format.

Action: Chair of SACIT undertook to work with UK Blood Service Quality Managers to ensure a rapid decision on approval of the label designs.

SP

5.3. **Implementation of ISBT 128**

Chair of UKBTS Forum confirmed that UKBTS Forum had requested proposals for a full implementation of ISBT 128. It was noted that SACIT had already held a workshop to take this forward and would be preparing detail proposals in due course.

SP

6 **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS**

6.1. **Evaluation of Efficacy of Prion Removal Filters – JPAC 06-04**

Paper JPAC 06-04, prepared by the SACTTI Working Party on vCJD, was received discussed and approved.

In an exchange of information on prion filtration developments, the following topics were touched upon.

- A tendering process for the proposed evaluations is in hand.
- Some uncertainty remains about the sources of funding for the various elements of the planned evaluation of efficacy.
- The Irish Blood Transfusion Service Board is undertaking a phased clinical assessment of the Pall prion reduction filter. The first phase – 20 recipients of a single red cell unit – is near completion. No acute adverse reactions have been reported. Subjects are being followed to detect any evidence of serological complications. The next phase will involve transfusion of 80 recipients who will be monitored for unexpected adverse events and change in haemoglobin following transfusion. The expectation was that the authorities in the Republic of Ireland may decide on full implementation towards the end of 2006 at an estimated cost of 14 million Euros (140,000 units).

Action

Operational issues noted:

- The current PALL device requires sterile docking.
- Leucocyte filtration is still required as a separate process.
- Red cell losses due to the two filtration steps are such that a standard volume donation yields about 35 grams of haemoglobin in the final product – this will require a change in specification.

Action: BMc will prepare a brief update report on the operational and financial issues and the progress of the trials for the next UKBTS Forum meeting on 21st April 2006.

BMc

6.2. **Donor Selection Criteria – MSM**

JPAC received and discussed papers JPAC 06-17 “Notes of SACTTI/SACCS D Task Group to discuss MSM Position Statement” and JPAC 06-18 “Evaluation of the de-selection of MSM and TT-HIV risk in England and Wales 2002-2004”

It was noted that there was pressure in many countries, from the Gay community, to relax or remove current restrictions on donation on the grounds that these are inappropriately discriminatory. A number of countries have reviewed their donor selection criteria in response to this pressure. Some countries have relaxed selection criteria for MSM while some have concluded that the current restrictions remain appropriate.

6.2.1. **Review of UK Blood Services policy:**

Paper JPAC 06-18 summarises the epidemiological evidence concerning the effect of possible relaxation in selection criteria. This paper, with the final conclusions, will be submitted for consideration and decision by MSBTO at its June 2006 meeting. This decision will form the basis of UK BTS policy for the forthcoming year.

LL

6.2.2. **Position Statement for UK Blood Services web site:**

There was agreement that there is a pressing need for a clear evidence based description of the present situation. A working group representing the UK Blood Services plans to provide a draft statement for wide discussion during March 2006.

LL

6.2.3. **Scientific basis:**

JPAC members stressed two points. 1) All statements concerning donor selection policies must make it explicit that policy is based on authoritative assessment of the most up to date scientific evidence. 2) Any recommendation made by JPAC on this issue must be based on the principle that it should not in any way detract from recipient safety.

A decision is still required on the timing of publication of the position statement once completed. Should it await the MSBTO deliberations or is there a requirement to publish before June 2006? Action: Chair of JPAC

BMc

6.3. **Influenza Pandemic**

Two papers from SACTTI have been received (JPAC 06-19 “Pandemic Influenza: SACTTI response to questions from SACCS D 7th November 2005” and JPAC 06-20 “Questions from the NBS Infection Control Committee: Influenza Pandemic”). After extensive discussion it was agreed that there would be value in a single concise JPAC document summarising the key issues for Blood Services.

Post meeting note: During the 29th meeting of the SP-GS in Brussels (14th to 17th March 2006) a short paper was drafted and agreed by an ad hoc subgroup lead by Prof.

Action

George Andreu of the French Blood Service. This paper will be included as an appendix to the 13th CoE guide and will be submitted to the European Committee of experts SP-HM. Circulated for information to members of JPAC.

7. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS
7.1. pH of Platelet Concentrates: version 6 – JPAC 06-05

This is a revision of a JPAC paper taken to the CoE SP-R-GS by Virge James 3 years ago, version 5 2003, which recommended pH limits of 6.4-7.4 for platelets at the end of their shelf life. This was accepted by CoE SP-R-GS and appeared in the 10th Edition of the CoE guidelines. The updated paper, version 6, includes data which suggests that there is no relationship between *in vitro* pH at levels greater than 6.2, and *in vivo* platelet viability as measured by radiolabelled recovery and survival of autologous platelets, and recommends that the upper specification limit be removed.

SM asked JPAC to:

- Endorse the recommendation that the upper limit of pH at the end of platelet shelf life be removed.
- Recommend that this specification be amended in the EU Directive and Statutory Instrument.

JPAC endorsed this recommendation and agreed that BMc could take this to the CoE SP-GS meeting in Brussels on 14th March, as this is the most appropriate route to get a change to the EU Directive.

Post Meeting Note: AT SP-GS this issue was discussed and it was agreed that a paper is to be produced for the spring 2007 meeting.

7.2. Summary report on component quality of red cells filtered using the Pall prion reduction device (Leukotrap® Affinity Prion Reduction Filter, LAPRF) – JPAC 06-06

The above paper was received and discussed. SACBC requested JPAC to:

- (1) Accept *in vitro* data of red cell quality as suitable for use
- (2) Consider the proposed options to address the reduction seen in Hb content, particularly whether consideration should be given to introducing a reduction in the specification for Hb.

The following points were made in discussion:

- It was noted that ESOR are reviewing an earlier risk assessment on the introduction of this technology at the request of the Prion Reduction Working Group. A report of this work would be requested for JPAC. Action: CJS. **CJS**
- Were the packs tested in the cold? – SM undertook to check this. **SM**
- The main concern noted was that the Pall process reduces the haemoglobin content of a red cell pack by about 25% i.e. not compliant with current specifications.

Action: (1) The Chair of SACCTM was requested to consult and report on the clinical implications of such a reduction in haemoglobin content of red cell units. **DN**

(2) The Chair of SACBC was requested to liaise with the Prion Reduction Working Group and report on its recommendations on this issue. **SM**

8. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**8.1. Geographical risk of disease – work with Health Protection Scotland to improve Donor Selection Guidelines – JPAC 06-07**

JPAC welcomed this proposal to align the donor selection information process with an established authoritative source of information.

8.2. Report to JPAC from the SACCSO – February 2006 – JPAC 06-08

Report from the Chair of SACCSO was discussed.

Changes to the membership were noted and approved.

Changes to the following items in the Donor Section Guidelines were approved:

Multiple Sclerosis - Change Notification No 2
 West Nile Virus – Change Notification No 3
 Age – Change Notification No 4
 Psoriasis – Change Notification No 6
 Tissue and Organ Recipients – Change Notification No 7
 Infection-Acute – Change Notification No 8

8.3. Influenza – Acceptance of donations: timing in relation to flu symptoms

Paper JPAC 06-19 notes that the current DSG states that donors who have had acute infections, (including flu), cannot be accepted, “Less than two weeks from recovery” and, “Less than seven days from completing systemic antiviral treatment.”

The following wording is included in the Blood Safety and Quality Regulations (BSQR) and is thus a legal requirement:

“After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

- Fever >38°C – 2 weeks following the date of cessation of symptoms
- Flu-like illness – 2 weeks after cessation of symptoms”

SACTTI had made the following recommendation in paper JPAC 06-19: “... if a donor subsequently becomes unwell with flu-like symptoms developing up to 48 hours following donation, the donation should be recalled.”

JPAC noted that SACTTI had sought specialist virological advice. Nevertheless JPAC members were unable to accept the recommendation to shorten the “ recall required” period from 2 weeks to 48 hours. The grounds for this caution were that there was no information on which to base a prediction of the likely duration of pre-symptomatic viraemia in humans infected with avian influenza virus or possible variants with greater virulence for humans.

Action: Chair of SACTTI undertook to seek further opinion and if possible report to the next JPAC Executive Working Group meeting in May.

LL

8.4. Previously Transfused Cadaver Donors

The JPAC Chair reported that MSBTO had, at its meeting on 24 January 2006, accepted a recommendation from its Sub-group on vCJD transmission risk from donated bone and tissues concerning the exclusion of previously transfused cadaver donors.

Action

Action: A Change Notification will be prepared and issued once the official record of the above MSBTO meeting is received.

**BMc,
DH**

8.5. **Disability Discrimination Act – update**

Under the leadership of Dr Elizabeth Caffrey (NBS) a number of groups had been established to produce recommendations for the Services to comply with the requirements of this Act.

Action: JPAC Chair to seek information from Dr Caffrey and report to the next JPAC Executive Working Group meeting on 24th May 2006.

BMc

8.6. **Donor Adverse Events**

Chair of SACCSD report that discussions have been initiated with MHRA.

9. **UKBTS FORUM UPDATE – JPAC 06-09**

MM went through the notes from the UKBTS Forum meeting on 4th November 2005 and 13th January 2006. The issue of risk information on blood components labels is dealt with in item 5.2.

10. **REPORT FROM MSBTO MEETING ON 24TH JANUARY 2006**

Minutes from the last MSBTO are still awaited. CJS will circulate the relevant information/actions when these have been received.

CJS

11. **REPORT ON JPAC REVIEW – JPAC 06-10**

The Chair of JPAC introduced the redrafted report and noted that this had been approved by the UKBTS Forum. JPAC approved the report and outline JPAC workplan.

Action: SAC workplans to be finalised and incorporated into a business plan for JPAC 2006/2007 and beyond for submission to the UKBTS Forum.

BMc

12. **ANY OTHER BUSINESS**

12.1. **Relationship between JPAC and the Quality Managers of the 4 UK Blood Services**

The Chair of JPAC reported that a UKBTS Quality Managers group has been formed at the request of the UKBTS Forum and is due to meet shortly. It was proposed to ask this group to nominate one of their members to become a member of JPAC. JPAC endorsed this suggestion.

12.2. **Standing Advisory Committee on Plasma for Fractionation**

It was agreed to stand down the Standing Advisory Committee on Plasma for Fractionation, since UK plasma is not currently being used for fractionation.

12.3. **British Blood Transfusion Society Annual Scientific Meeting – Bournemouth 2006**

Action

The Chair of JPAC reported that a request had been received from the BBTS for JPAC to have a session covering the changed way or working of JPAC, the web site etc. on Friday 22nd September.

The following was proposed at the JPAC Executive Working Group Meeting:

JPAC:

General background, communications etc. Brian McClelland 30 minutes

Knowledge Base:

Evidence base for transfusion Chris Hyde 15 minutes
 JPAC & National Library for Health Susan Brunskill 15 minutes

Standing Advisory Committees:

Blood Components Sheila MacLennan 10 minutes
 Care & Selection of Donors David Hutton 10 minutes
 Information Technology Stuart Penny 10 minutes

12.4. **MHRA – Hospital Blood Bank Inspections**

BM informed the group that 371 hospitals had submitted reports. The MHRA were planning to inspect 60 hospital blood banks throughout the UK. The inspections will be completed prior to April 2007.

12.5. **Consultation process on the proposed merger of NIBSC and HPA**

SI thanked the members of JPAC for their response to the NIBSC consultation. SI suggested that HPA could be brought into the JPAC forum.

Proposals to be developed and brought to JPAC on enhanced collaboration with HPA. Action: SI and BMc. This would also be an agenda item for the next JPAC meeting.

**SI,
 BMc &
 CJS**

The meeting closed at 15:25

15. **DATE AND VENUES OF FUTURE JPAC MEETING**

2006: Wednesday 21st June at the West End Donor Clinic in London
 Wednesday 1st November at the West End Donor Clinic in London