

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 27th meeting of JPAC held at the Royal College of Obstetricians and Gynaecologists, London, on Friday 21st November 2003

Second day of Special 2-day JPAC Meeting

Meeting commenced at 09.30 am

JPAC MEMBERS PRESENT

Dr Frank Boulton	(FB)	-	Standing Advisory Committee on Care and Selection of Donors
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 and Stem Cells
Dr Stephen Inglis	(SI)	-	Director, National Institute for Biological Standards and Control
Dr Virge James	(VJ)	-	Chair, Joint UKBTS/NIBSC Professional Advisory Committee
Dr Liz Love	(LL)	-	Standing Advisory Committee on Transfusion Transmitted Infection
Dr Sheila MacLennan	(SM)	-	Standing Advisory Committee on Blood Components
Dr Brian McClelland	(BM)	-	Standing Advisory Committee on Clinical Transfusion Medicine
Dr Morris McClelland	(MM)	-	Medical Director, Northern Ireland Blood Transfusion Service
Dr Tony Napier	(TN)	-	Acting Medical Director, Welsh Blood Service
Dr Angela Robinson	(AER)	-	Medical Director, National Blood Service
Mr Chris Turner	(CT)	-	Medicines and Healthcare Products Regulatory Agency
Prof. Stan Urbaniak	(SU)	-	Standing Advisory Committee on Immunohaematology
Miss C J Smith	(CJS)	-	JPAC Secretary

SAC, SUB-COMMITTEE AND WORKING PARTY MEMBERS PRESENT

Mr Neil Beckman	-	National Blood Service, Birmingham (<i>Sub-Committee on Technical Aspects</i>)
Ms Angela Brazier	-	National Blood Service, Newcastle (<i>SAC Immunohaematology</i>)
Dr Moji Gesinde	-	National Blood Service, Leeds (<i>Sub-Committee on Apheresis</i>)
Dr David Howell	-	National Blood Service, Colindale (<i>Sub-Committee on TMRRG</i>)
Dr David Hutton	-	UKBTS (<i>Working Party on DSG</i>)
Dr Derwood Pamphilon	-	National Blood Service, Bristol (<i>Sub-Committee on Stem Cells</i>)
Dr Chris Prowse	-	Scottish National Blood Transfusion Service, Edinburgh (<i>SAC Blood Components</i>)
Dr Serge Six	-	National Blood Service, Plymouth (<i>Working Party on DSG</i>)
Dr Ruth Warwick	-	National Blood Service, Colindale (<i>Working Party on T-DSG</i>)
Dr Philip Yates	-	Scottish National Blood Transfusion Service, Aberdeen (<i>SAC Tissues and Stem Cells</i>)

GUEST

Dr Heidi Doughty	-	National Blood Service, Birmingham
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1. **APOLOGIES** **ACTION**

Mr Paul Ashford **(PA)** - Standing Advisory Committee on Information Technology
Prof. Ian Franklin **(IF)** - Medical Director, Scottish National Blood Transfusion Service
Mr Chris Rudge **(CR)** - Medical Director, UK Transplant

2. **MINUTES OF THE MEETING ON 12th June 2003**

The minutes of the last meeting held on 12th June 2003 were approved.

3. **MATTERS ARISING FROM THE MINUTES OF THE LAST MEETING**

Only matters not on the agenda are minuted in this section.

3.1. **Small Pox Vaccination – Concessionary Letter (Tissues) – item 3.15.**

Concessionary Letter was issued to the Quality Managers of the 4 Services on 25th September 2003.

3.2. **Links with the Health Protection Agency – item 5.2.**

VJ has written to and received a reply from Prof. Brian Duerden, Director Clinical Quality at the Health Protection Agency (HPA).

Prof. Duerden states in his letter:

“We certainly need to enhance the links between the Health Protection Agency and the National Blood Service. As our systems of Advisory Committees and Working Groups develop guidelines and policies, I will try to ensure that the Transfusion Services are appropriately included in any of the discussions and/or notified of the policies that we are bringing forward.

I have copied you letter and my response to our Scientific Secretary which provides the support for our Committees so that they know to include you in appropriate circulations”.

3.3. **Feedback from Day 1 of Special 2-Day JPAC Meeting – 20th November 2003**

VJ explained the role of JPAC and its relationship to other bodies:

- UK Forum
- National Blood Transfusion Committee (NBTC)
- Blood & Tissue Safety Assurance Group (BTSAG)
- Health Protection Agency (HPA)
- Microbiological Safety of Blood and Tissues (MSBT)
- Council of Europe (CoE)
- European Union (EU)

Ruth Warwick gave a review of tissues.

Alan Bell (DoH) explained the role of the DoH in formulating policy. The EU Directive on tissues and cells is expected to be formally adopted in the Spring of 2004. The Competent Authority could be a newly created Human Tissue Authority. Accreditation of Tissue banks has been extended to March 2004.

George Galea discussed outstanding issues in Tissues.

ACTION

Stephen Inglis gave an update on the function of the NIBSC.

Serge Six explained the development of the JPAC Resource area on the web site. A lively discussion of how to develop this area took place. It is hoped to launch the area on 1st April 2004.

Day 1 of the Special JPAC meeting was also attended by:

Dr Liz Caffrey (NBS Cambridge), Dr Brian Dow (SNBTS), Mr John Savage (NIBTS), Dr Susan Thorpe (NIBSC), Mrs Jane Pearson (NBS Cambridge) and Mr Alan Bell (DoH)

The following JPAC members were not able to attend day 1:

Dr Liz Love, Dr Morris McClelland, Dr Angela Robinson, and Mr Chris Turner.

Post Meeting Note

As requested only hard copies of the presentations given by Ruth Warwick, George Galea and Stephen Inglis have been circulated by CJS.

4. **EUROPEAN UNION DIRECTIVE 2002/98/EC**

AER updated JPAC on the EU Directive 2002/98/EC.

- The Regulatory Committee Meeting held in September 2003 was the last chance to amend the Technical Requirements re Article 29: b) c) d) e) and g).
- Richard Gutowski is the DoH Representative.
- The formal text has been approved and circulated to SAC Chairs.
- A decision is still awaited on Article 29: a) h) and i).
- AER will circulate the new text to JPAC.
- AER thanked the SAC Chairs for their comments, as continued input from JPAC committees is important in formulating policy at EU level.

5. **CLARIFICATION OF THE EU DIRECTIVE ON INVITRO DIAGNOSTIC DEVICES**

IVD Directive comes into force on 6th December 2003. There are concerns about the interpretation of this Directive by MHRA. The merger of the MCA and MDA into MHRA is still progressing. CT agreed to clarify the following issues:

- Copper sulphate - this reagent is not CE marked. Can the Blood Services continue to use it?
- PCR techniques
- Reagents used in H&I Laboratories where "in house" reagents only are available.

Action: CT to give the MHRA view

VJ to gather together all the queries from the UK Blood Services and send to CT

6.

UK FORUM

ACTION

AER and TN reported back from the UK Forum.

6.1. **Chair of Joint UKBTS/NIBSC Professional Advisory Committee**

This post has been re-advertised and AER is organising interviews to take place in December 2003/January 2004.

6.2. **MSBT**

Prof. Lindsey Davies, new Chair of MSBT, is undertaking a review of the MSBT.

Action: AER to send relevant papers to CJS to circulate to JPAC.
VJ to co-ordinate JPAC response to the proposed changes.

7.

FEEDBACK FROM BBTS 2003

Caroline Smith and Serge Six reported on the JPAC stand at the BBTS Annual Scientific meeting held in Manchester in October 2003. It was felt that this went well and that JPAC should have a small similar stand at the ISBT in Edinburgh in July 2004.

Action: CJS to contact Judith Chapman

FB offered to place an article about the web site in Transfusion Today.

Action: VJ to write the article

8.

7TH EDITION OF THE "RED BOOK" 2004

8.1. **User Questionnaire Results – JPAC Enc. 03/49**

This was well received, although it was felt that as it was distributed only to recipients of the printed book the results were non-representative. A follow up survey was suggested, possibly to run the survey on the web site.

Action: New Chair of JPAC

8.2. **Progress Report**

VJ requested chapters from the SAC Chairs by the end of January 2004. These chapters will need to take into account the EU Directive.

CT was asked whether the MHRA inspections will use the EU Directive or the Red Book in future. CT replied that as the EU Directive aims at minimum standard and the Red Book reflects the more stringent requirements in the UK, both the Red Book and the EU Directive will be used. AER stated that the Red Book is crucial for updating the EU Technical Directives.

GG informed JPAC that with regard to stem cells Phil Yates has been working on microbiology inconsistencies this will not be ready until May 2004.

DP reported that Tissue Laboratories, inspected by MHRA, use both the Red Book and Code of Practice for Tissues. CT replied that they will use what is available and Red Book defines best practice.

RW asked CT if the MHRA are applying the same standards to non Blood Service Tissue Banks. CT informed JPAC that MHRA are looking at best practice. There are 4 Inspectors who are aiming at consistent standards.

ACTION

9. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS**

SM explained the background to the following:

9.1. **Bacterial Contamination Blood Pack Information – JPAC Enc. 03/49**

Action: SM to change title and then send to VJ to send to the UK Forum

9.2. **Current International Position with Extension of Platelet Shelf Life to 7 Days – JPAC Enc. 03/50**

Action: Statement of the JPAC view required from SM.

9.3. **pH of Platelet Concentrates – JPAC Enc. 03/51**

Action: SM to continue looking at higher level.

9.4. **Maximum Storage Time of FFP, Cryoprecipitate, Cryodepleted Plasma and MB-Treated FFP – JPAC Enc. 03/52**

JPAC endorses this paper with comments regarding testing added.

Action: SM to add comments

9.5. **Cold Storage of FFP – JPAC Enc. 03/53**

Action: SM & FB to provide agreed wording which will be circulated via JPAC.

9.6. **TRALI Reduction Strategies**

- a) FFP from male donors only. This could provide 90% of FFP requirements.
- b) Overnight holds at 4°C (reduces VIII by 30%), overnight hold at ambient temperature – would enable more selective processing (work in the NBS is being carried out by Rebecca Cardigan).

Action: JPAC asked SACBC to produce a paper on the pros and cons of overnight hold.

9.7. **Methylene Blue Cryo Prep**

NBS and SNBTS are working on this product. The demand for this product is unclear. Methylene Blue Cryo to be included in the next edition of the Red Book in 2004.

Action: Chris Prowse, Bruce Cuthbertson, Brian McClelland and SM to produce a paper on production requirements. SM to bring to next JPAC meeting on 18th February 2004. Brian McClelland to liaise with VJ and Lorna Williamson regarding audit of current use.

10. **STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**

10.1. **Safety of Blood Leaflet – JPAC Enc. 03/58**

JPAC endorsed an interim reprint of the leaflet with the new information on HTLV included, both on the picture page and the written page. In future a new redesigned leaflet may be required. This will be a long-term project.

ACTION

Action: FB to: 1) arrange reprint (via the NBS)
2) start the process of design for a new leaflet with the SACCSO.

10.2. **Minutes of the SACCSO Meeting on 4th June – JPAC Enc. 03/60**

- Appendix 1 – Work List for Annual Review of JPAC Activities

Action: FB to update, with regard to revised guidelines, for the JPAC meeting on 18th February 2004.

- Report from the Apheresis Sub-Committee – Item 10

The Apheresis Sub-Committee is reminded that changes need to be approved by the SACCSO and then endorsed by JPAC.

10.3. **DSG**

The launch of the new technical version of the current DSG and new version of the DSG (changes to selection criteria) was discussed at length.

It was agreed to launch the technical version on the first Monday in March 2004 (which is 1st March) and the new version of DSG can be launched at the same time if ready. Otherwise it will be launched when all changes to criteria have been agreed by JPAC.

Action: Serge Six and David Hutton to ensure that all proposed changes to selection criteria are presented at the JPAC meeting on 18th February 2004.

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

11.1. **4th Edition of the Handbook of Transfusion Medicine**

BM updated JPAC on the progress of the next edition of the Handbook of Transfusion Medicine.

- Draft Handbook will be sent to members of the SACCTM before the end of November 2003.
- Small run of books by TSO is proposed.
- Use web site as main point of access.
- Strengthened links with BCSH and Systematic Review Evidence Base working with BM and FB.

12. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

12.1. **Concessionary Letter for Management of DAT Positive Blood Donors – JPAC Enc. 03/63**

JPAC and the Medical Directors present endorsed the concessionary letter with a few minor amendments.

Action: SU to forward amended letter to VJ to send out

12.2. **Standards**

SU reported that the SACIH are working very closely with NIBSC.

13. **STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY** **ACTION**

Apologies received from Paul Ashford – No report.

14. **STANDING ADVISORY COMMITTEE ON PLASMA FOR FRACTIONATION**

Nothing to report.

15. **STANDING ADVISORY COMMITTEE ON TISSUES AND STEM CELLS**

15.1. **Correspondence with CJD Incident Panel – JPAC Enc. 03/66**

GG drew the group's attention to the last paragraph of the letter dated 21st August 2003 from Philippa Edwards, CJD Policy Team at the Department of Health which states:

“I can assure you that the Department is taking steps to take forward the risk assessments that are required in order to allow MSBT and the CJD Incidents Panel to develop the appropriate risk management guidance”.

15.2. **SEAC**

Work on bone marrow is completed and has gone to the various committees. There is a meeting on 26th November 2003 followed by consultation with Users. A public meeting of SEAC is planned for February 2004. Tissues will follow the same route.

15.3. **Inconsistency in Tissue Chapters**

Most of this work has been completed by Phil Yates.

15.4. **Liability when asked to send Tissues outside the United Kingdom**

GG reported that this issue is still unresolved. AER explained that tissues come under the Consumer Protection Act and therefore the product is liable for any defect. However, for many exported tissues there is no alternative source, and the tissues are life-saving, and therefore the risk benefit is in favour of providing the tissues.

Action: DP and GG to write to AER explaining the problems and AER will seek legal advice.

16. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION**

16.1. **Definition of Position Statements**

What is, and what is not, a Position Statement was discussed at length.

Position Statements can be split into two categories, depending on who they are aimed at.

1. **Public Position Statements** – issues/hot topics of concern to be used for the media etc. and therefore can be located on the web site unrestricted.
2. **Service Position Statements** – these are current advice for the Services and therefore are for the JPAC Resources restricted area.

Action: VJ

16.2. **Calculated Microbial Risk From Blood Transfusion – 03/69**

ACTION

LL explained the background of this paper (NBS and Wales) for the group.

Action: LL to provide VJ with a summary of agreed residual risk for the public area of the web site.

16.3. **SACTTI Position Paper: On the duration of blood donation archive sample storage – JPAC Enc. 03/70**

JPAC agreed that this paper was a Service Position Statement.

NIBSC has made a case to the DoH for a National Archive Facility as they don't have space. Stephen Inglis to take to the UK Forum. A joint approach from NIBSC and the UK Forum to the DoH on requirements for archive storage may be helpful.

16.4. **Proposal to reduce the deferral period for piercing from 12 to 6 months – JPAC Enc. 03/71**

JPAC agreed that this paper was a Service Position Statement.

SACTTI recommendation:

“It is recommended that the deferral period for piercing could be reduced from the present 12 months to 6 months, only on the demonstration of a negative anti-HBc test. In the situation where an anti-HBc test is positive, then the donor should be debarred as in 2.7 (Red Guide 6th Edition p21).”

This was endorsed by JPAC.

16.5. **UK BTS Position Statement on Creutzfeldt-Jakob Disease updated 29th October 2003 – JPAC Enc. 03/72**

This revised Position Statement was endorsed by JPAC.

Action: VJ to forward for posting on the web site.

16.6. **Optimization of Microbiology Testing for Tissue and Stem Cell Donors – JPAC Enc. 03/73**

LL explained the background of this paper, which when finalised will be a Service Position Statement.

A small Working Group will be setting up including: Phil Yates (Chair), Ruth Warwick, Roger Eglin, Brian McClelland, Philip Mortimer, Richard Tedder and David Hutton. This Working Group will be given a 6-month reporting time scale.

JPAC agreed to the formation of the Working Group.

16.7. **Draft Position Paper on CMV Seronegative vs Leucodepleted Blood Components for at Risk Recipients – JPAC Enc. 03/76**

LL explained the background of this paper.

BCSH will advise Users/Clinicians. JPAC will advise the Services.

Action: Medical Directors/FB

16.8. **Position Statement on West Nile Virus, 8 November 2003 – JPAC Enc. 03/77**

ACTION

Post Meeting Note from LL:

Following Roger Eglin's advice (24th November 2003) in the light of updated figures from the US, the original deferral period as stated in v 1.0 is valid and there is no need to update the statement on the web site.

16.9. **Joint Position Statement on Severe Acute Respiratory Syndrome: Blood and Blood Components, Version 4, 12 November 2003 – JPAC Enc. 03/78**

This revised Position Statement was endorsed by JPAC.

Action: VJ to forward for posting on the web site.

16.10 **Draft Position Statement: NAT Testing, 13 November 2003 – JPAC Enc. 03/79**

This is NBS work in progress and was tabled by LL for comment. LL drew the group's attention to page 5, number 4.

Action: All – comments to LL

16.11 **Recommendations for the Minutes of the SACTTI Advisory Group on Blood Parasites held on 26th June 2003 – JPAC Enc. 03/83**

JPAC accepts the recommendations. Topics for consideration are:

- Parvo Virus
- Leishmaniasis – Service men and women from the Gulf (request information from MoD).

Action: LL to send leishmaniasis paper to Heidi Doughty.

17. **Items raised by NIBSC**

No items were raised.

18. **Items raised by UK Transplant**

Apologies received from Mr Chris Rudge.

19. **ANY OTHER BUSINESS**

No more items raised.

20. **DATE AND VENUE OF NEXT MEETING**

Wednesday 18th February 2004. Please note this meeting is being held at Birmingham New Street.