

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 26th Meeting held at West End Donor Clinic, London on Thursday 12th June 2003

Meeting commenced at 11.00 am

PRESENT

| | | | |
|---------------------|--------------|---|---|
| Mr Paul Ashford | (PA) | - | Standing Advisory Committee on Information Technology |
| Dr Frank Boulton | (FB) | - | Standing Advisory Committee on Care and Selection of Donors |
| Dr Morag Ferguson | (MF) | - | National Institute for Biological Standards and Control |
| Prof. Ian Franklin | (IF) | - | Medical Director, Scottish National Blood Transfusion Service |
| 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 Tony Napier | (TN) | - | Acting Medical Director, Welsh Blood Service |
| Dr Angela Robinson | (AER) | - | Medical Director, National Blood Service |
| Miss C J Smith | (CJS) | - | JPAC Secretary |

1. **APOLOGIES** **Action**

| | | | |
|----------------------|-------------|---|--|
| Dr Bruce Cuthbertson | (BC) | - | Standing Advisory Committee on Plasma for Fractionation |
| Dr Morris McClelland | (MM) | - | Medical Director, Northern Ireland Blood Transfusion Service |
| Mr Chris Rudge | (CR) | - | Medical Director, UK Transplant |
| Mr Chris Turner | (CT) | - | Medicines and Healthcare Products Regulatory Agency |
| Prof. Stan Urbaniak | (SU) | - | Standing Advisory Committee on Immunohaematology |

2. **MINUTES OF THE MEETING ON 14th February 2003**

The minutes of the last meeting held on 14th February 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. **Sub-Committee on Apheresis** – item 3.1.

The Terms of Reference have been changed to reflect that this committee is accountable to both the SAC on Blood Components and the SAC on Care and Selection of Donors.

3.2. **vCJD** – item 3.4

GG has written to SEAC – JPAC Enc. 03/39

- 3.3. **Recommendations from the Joint Meeting on Granulocytes – item 3.6.** **Action**
- Medical Directors have made their lead clinicians aware of these recommendations.
- 3.4. **EU Directive – item 4.1.**
- AER is taking to the next National Hospital Transfusion Committee meeting.
- AER to send CJS copies of two presentations given at the RSM on 5th February 2003 for onward circulation to JPAC. ***Post Meeting Note: Presentations circulated to JPAC members on 16th June 2003.***
1. European Directive on Blood Safety Implication for UK Blood Services – Martin Gorham, NBS
 2. The EU Blood Directives: Implications for the IBTS and for Hospital Blood Banks – Dr W Murphy, IBTS
- AER informed JPAC that the MCA have merged with the MDA and the new organisation is called the Medicines and Healthcare Products Regulatory Agency (MHRA).
- 3.5. **HBV paper – item 6.3.**
- Expansion of this paper to include all risks of transfusion. The final agreed list of residual risk could go on the web site.
- Action:** BM is progressing list of non-infective risks. LL & SACTTI are progressing infective risks. **BM &
LL**
- 3.6. **Implementation date for 6th Edition of Red Book - item 6.7.**
- This is now up on the website.
- 3.7. **JPAC website and SHOT – item 7.2. (a)**
- The SHOT website is www.shotuk.org and is hosted by the WBS. JPAC is no longer involved.
- 3.8. **DAES - Donor Adverse Event Surveillance (NBS) – item 7.2. (b)**
- The JPAC Website Steering Group agreed that although collection of information about DAES from the 4 UK Services was important the current proposals are for a “management tool” type data collection. This is not within the remit of JPAC, therefore it is not taken forward. The NBS has set up a DAES which is available to the other Services should they wish to partake.
- 3.9. **pH of platelets – CoE guidelines – item 8.**
- SM is progressing a paper for the CoE. The paper was requested by November 2003 for discussion at the February 2004 SP-R-GS meeting.
- Action:** SM **SM**
- 3.10. **Correction to SACCTM minutes – item 9.**
- Keith Wilson has given the correction to BM.
- 3.11. **7-day platelets – item 10.1.**
- Action:** SM and SACBC are progressing on behalf of JPAC **SM**

3.12. **Components which have completed phase 0 validation – item 10.3.** **Action**

Pending.

3.13. **PI Framework – item 10.4.**

Work on the Pathogen Inactivation framework is ongoing. VJ requested that SM and LL submit a paper for the UK Forum meeting on 1st August 2003. The paper should be sent to VJ who will forward to the UK Forum.

Action: SM, LL and VJ

**SM, LL
& VJ**

3.14. **Concessionary Letters – item 10.5.**

VJ informed JPAC that Dr Bruce Cuthbertson is now the Quality Manager for SNBTS.

3.15. **Smallpox vaccination – item 11.3.**

The current concessionary letter does not include reference to skin donation.

Action: GG to ask David Hutton to write a concessionary letter regarding tissues and smallpox vaccination and VJ will issue.

GG

3.16. **Safety of Blood Leaflets information sheets – 11.4.**

VJ updated JPAC on the progress of the information sheets to support the safety of blood leaflets. The next meeting of the group is on 12th September 2003 when the current Focus Group trials will be reported. It is hoped that these will be on the JPAC website and available for the start of the University term.

4. EUROPEAN UNION DIRECTIVE 2002/98/EC

AER updated JPAC on the EU Directive 2002/98/EC. This directive will be enforced in February 2005.

- An Expert meeting has been held to tackle Annexes A-F, involving the EBA, Willie Murphy and Karl-Friedrich Bopp.
- It has been agreed that the CoE Expert Committees will produce draft updates annually.
- The Directive articles laid down in the EU recommendations will be legally binding and not guidelines.
- The CoE and EBA experts are working together to co-ordinate agreed single input from the EU countries.

Current groups are:

1. Quality and safety requirements
2. Autologous transfusion
3. Haemovigilance

All these annexes will have to be agreed at an EU Regulatory Committee by a voting procedure before February 2005. Transposition of the Directive into UK law is undertaken by the Government.

AER to send Draft Revision No 2 of the Directive to CJS for circulation to JPAC.

Post meeting note: Circulated to JPAC members on 16th June 2003.

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| 5. | UK FORUM | Action |
|-----------|-----------------|---------------|

5.1. **Feedback from the UK Forum meeting held on 23rd May 2003 – Virge James**

VJ had submitted the JPAC Annual Report to the UK Forum – JPAC Enc. 03/26.

VJ felt this was a very positive meeting and the UK Forum confirmed that JPAC is the “source of advice” the UK Forum needs. There were a few comments, but the minutes are not yet available.

Main comments:

5.1.1. **SACIT**

The UK Forum noted the good work done by this SAC.

The position of the SACIT in JPAC is still being raised – VJ feels strongly that it should be part of the JPAC structure.

ISBT 128 (2) UK Forum is awaiting a business case from PA.

Relabelling of US plasma – QMs of the 4 Services did not think this was a major problem and therefore whilst the issue has been raised it will not be pursued by the UK Forum, but by individual Services.

5.1.2. **JPAC Position Statements on the web site**

Position Statements should be seen by Publicity/Customer Relations before they are posted on the website to ensure appropriate wording etc., and also to make all 4 Services Customer Relations Departments aware of the current position.

JPAC agreed that these statements should be sent to Chris Hartley NBS, in the first instance, and then to the Publicity Departments of the 4 Services for information.

5.1.3. **7th Edition of the Red Book**

The complete revision planned by VJ was discouraged as it is too early to be quite certain of what the requirements for 2005 would be; but bringing the publication more in line with the requirements of the EU was encouraged.

5.1.4. **Web site transfusionguidelines.org.uk**

All funding requested in the JPAC Annual Report (JPAC Enc. 03/26) had been approved by the UK Forum.

5.1.5. **JPAC Chair’s proposal for the future of JPAC**

VJ’s proposal for the future of JPAC, as outline in the JPAC Annual Report (JPAC Enc. 03/26), will be considered at the next UK Forum meeting on 1st August 2003.

5.1.6. **Implementing Change**

It was suggested that, to ensure rapid communication of changes required, the 4 MDs should have a system of discussing issues speedily.

5.2. **Feedback from MSBT - AER**

MSBT endorsed the SACTTI position statements on SARS and WNV and they recognised there needs to be a system for dealing with rapid response. The MSBT expressed a wish to be

linked into this process.

With respect to the recommended SARS deferral period, the MSBT felt that the scientific view should be followed (as recommended in the JPAC position statement) regardless of implementation issues.

Action

AER reported that the NBS had produced a critical pathway for control of change procedures. MSBT would like to be linked in with the process.

GG still felt that MSBT concentrated more on blood than tissues. BM reassured him that this had been fully discussed at MSBT and that the decision has been taken to establish a tissues sub-committee of MSBT.

Stephen Inglis asked for clarification of how issues arose and what path they followed. For example, if the Health Protection Agency (HPA) are aware of an emerging pathogen would they automatically think of the consequences for blood and tissues? A system needs to be introduced for this. The links with the HPA need to be developed.

Action: VJ

VJ

5.3. **Proposed 2-Day Special JPAC Meeting**

VJ put forward a proposal to hold a 2-day JPAC meeting later in the year. It was proposed to invite the chairs and secretaries of all the SACs, sub-committees and working parties to 1 day of the meeting and hold the JPAC meeting on day 2.

Action: VJ and CJS

**VJ &
CJS**

6. **CONCESSIONARY LETTERS**

VJ informed JPAC that as Dr Bruce Cuthbertson was now the Quality Manager for SNBTS further concessionary letters would bear his signature.

7. **RED BOOK ERRATA**

There had been some problems in the Chapter on Reagents. VJ had asked for Richard Knight's assistance and an errata slip would be issued.

Action: VJ

VJ

8. **COUNCIL OF EUROPE**

The draft of the 10th Edition of the CoE "Guide to the preparation, use and quality assurance of blood components" had been circulated to the SAC chairs.

Action: SAC Chairs send their comments to VJ by Friday 18th July.

**SAC
Chairs**

- AER informed JPAC that MSBT will be setting up a Tissues and Stem Cells sub-group. AER to remind Peter Doyle to be in contact with Rachel Green (the UK member) and George Galea.
- GG explained that an EU Directive on Tissues is expected next year, not including organs.

AER

| 9. | STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS | <u>Action</u> |
|-------|---|---------------|
| 9.1. | <p><u>pH Platelets</u></p> <p>SACBC to produce a paper on pH platelets for the CoE by November 2003.</p> | SM |
| 9.2. | <p><u>7 Day Platelets</u></p> <p>SACBC will produce a paper on this for JPAC.</p> | SM |
| 9.3. | <p><u>TRALI – prevention</u></p> <p>SACBC will look at overnight holds for plasma to reduce the incidence of TRALI, as this will enable selection of donations. They are currently gathering evidence from throughout the world.</p> | |
| 9.4. | <p><u>7th Edition of the Red Book</u></p> <p>A section on evaluation of apheresis systems will be added.</p> | |
| 9.5. | <p><u>Leucodepletion</u></p> <p>IF raised the issue of failures of leucodepletion with current monitoring systems. We need a UK prospective on this. The NBS have had no failures in the last 3 months. NBS will discuss with Processing in Scotland.</p> <p>Action: SM to take forward.</p> | SM |
| 10. | STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION | |
| 10.1. | <p><u>Position Statement on SARS – JPAC Enc. 03/40</u></p> <p>New version (updated 27th May 2003) is now on the website.</p> | |
| 10.2. | <p><u>Draft Position Statement on West Nile Virus – JPAC Enc. 03/41</u></p> <p>This was approved by JPAC after 2 amendments.</p> <p>Action: VJ to send to Chris Hartley for comment on wording and presentation, not content.</p> | VJ |
| 10.3. | <p><u>HBV</u></p> <p>Risk 1 in 1 million based on recent analysis.</p> <p>NBS (Roger Eglin) has been working on an outline proposal for a donor prevalence study (anti HBcore and HBV DNA), but this has been abandoned for the time being as the study will need to be huge to inform a decision on whether or not to implement either or both tests to reduce TT- HBV residual risk. SACTTI has requested sight of this paper.</p> | |
| 10.4. | <p><u>7th Edition of the Red Book</u></p> <p>Limited revision due to lack of time. The need for a separate and completely revised chapter is recognised and planned for 2004.</p> | |
| 10.5. | <p><u>Bacterial Contamination</u></p> <p>This WP has not met and therefore has been closed. Concern was expressed as this is a</p> | |

priority issue and we should have Quality Control Standards for monitoring skin contamination. LL stated that these would have to be very general as it was difficult to write a very specific standard.

Action

Action: LL will write a more general standard.

LL

10.6. **Emerging pathogens position paper**

BM stated the need to “go back to the drawing board” with this in view of recent developments (SARS and WNV).

Action: BM and LL to work together

**BM &
LL**

10.7. **Archiving sample storage**

Working on a paper.

10.8. **Draft outline paper on resource to support SACTTI – JPAC Enc. 03/47**

LL went through this paper for JPAC. The proposal was not supported as every SAC could ask for this type of support. It is clear that time for members of the JPAC Committee is a difficult issue. In the NBS this is being considered thoroughly.

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

11.1. **Handbook of Transfusion Medicine – JPAC Enc. 03/34**

The core text and tables of the Handbook on this site are the same as that of the printed Handbook of Transfusion Medicine, 3rd edition, published by The Stationery Office. The printed Handbook is the version approved by the Joint Professional Advisory Committee. From time to time there may be additional information and updates added to the site. These will be identified [by a different typeface...or whatever the experts advise] New material will also be announced in the Updates page of the site [which we may have to add]. This additional material is for information and does not affect the status of the printed 3rd edition.

11.2. **Notes for authors of Handbook of Transfusion Medicine 4th Edition – JPAC Enc. 03/35**

BM went through these notes for JPAC. BM informed JPAC that BCSH are involved in the Handbook through regular joint meetings between the SACCTM and the BCSH Transfusion Task Force.

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

12.1. **Donor Selection Guidelines**

Increases in sexually transmitted diseases are causing concern and are being monitored in case stricter guidelines are required.

12.2. **Pre-donation Hb testing (blood and apheresis donors)**

This was discussed at the Sub-committee on Apheresis meeting on 14th November 2002. FB read out the following from the minutes of this meeting:

5.6 **Haemoglobin estimation from apheresis donors**

MG discussed the results of an audit that had been performed in one of the NBS centres concerning the frequency apheresis donors had haemoglobin levels estimated at each visit. It was up to 4 times per visit for each donor. The group have, therefore, endorsed the following recommendations for platelet and plasma donors attending apheresis units.

Action

1. Regular apheresis donors do not require pre-haemoglobin screening.
2. All donors should proceed to donation and blood samples normally taken should include a venous sample for full blood count.
3. Procedures should be in place for donors with abnormal FBCs and for donors returning from deferrals or not attending for 6 months or longer.

FB stated that the SACCSD endorse these proposals. JPAC endorsed this stance.

Action: Concessionary letter

VJ

12.3. **Donors who have had acupuncture**

SACCSD wanted JPAC's approval for accepting as donors people who, though otherwise fit, have received acupuncture from practitioners registered with the General Osteopathic Council (now a statutory body). This was approved by JPAC.

Action: FB

FB

12.4. **Rule setting and implementation**

FB stated that this was highlighted by SARS and there are implementation issues. IF requested that FB and LL to look at what would happen if London becomes an endemic area (hit by SARS).

Action: JPAC requested that LL and FB to look into this and produce a paper.

FB & LL

12.5. **HTLV**

Donor Selection Guidelines and Safety of Blood Leaflet need to be updated to include sexual partners. **Action:** FB to ask SACTTI for their input.

FB

13. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

No report.

14. **STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY**

14.1. **Membership**

Dr Hafiz Qureshi, Consultant Haematologist, NBS Sheffield and University Hospitals of Leicester, has joined the SACIT

14.2. **Component Code Reference Table**

PA informed JPAC that there are 362 labels on the list. There are different labels for the same product in the 4 Services. SACBC and SACIT are setting up a small group to rationalise the list.

14.3. **UK CPRS**

UK CPRS is a NHSIA project, which involves a UK database of prescription drugs, would like to

include blood components to the list.

14.4. **BCSH Guidelines for Blood Bank Computing** **Action**

BCSH have agreed to update these guidelines. PA will be representing SACIT on the Editorial Writing Group which is being lead by John Revill.

14.5. **Chief Medical Officer's IT User Group**

Identifying IT standards which have an impact on blood transfusion.

Identified the Design Authority – transfusion needs are fed into the Design Authority
Mapping transfusion process from donor to patient.
SNOWMED CT – we need to have a way of influencing how these codes are used in the UK.
Looking at a project such as blood tracking – need to get evidence base to prove that these systems are beneficial.

14.6. **Red Book – Labelling chapter for stem cells**

The need for a labelling chapter for stem cells was recognised.

14.7. **Representative on British Society for Bone Marrow Transplantation**

Action: IF will discuss with Roger Eglin.

IF

14.8. **Plasma**

MF informed JPAC that plasma for anti-D manufacture will be tested for parvovirus B19 from January 2004.

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

No report.

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

16.1. **EU Directive on Tissues**

The EU Directive will require an adverse event reporting system. This will involve the Blood Services and BATB.

Action: GG to discuss with SHOT/Peter Doyle/NPSA

GG

16.2. **Consent to Tissue Donation – JPAC Enc. 03/16 (re-circulated)**

It was agreed to send this document to the SNBTS legal advisers reminding them that it is a UK document. Then back to the WP to be presented in position statement style to then go to Customer and Public Relations and the website. **Action:** GG and VJ

**GG &
VJ**

16.3. **CJD Incidents Panel and Tissue Donation – JPAC Enc. 03/39**

GG had sent JPAC comments to Prof. Banner. No response has been received.

16.4. **DoH Group Policy Collaborative**

GG reported that the DoH have set up a group looking at the longer term management of

organs and tissues. Lindsay Davies (Chair of MSBT) is undertaking a root and branch review of MSBT. Richard Gutowski is the contact at the DoH.

16.5. **HTLV testing of organ and tissue donors**

Action

There is difficulty in getting a rapid diagnostic test. HPA remit is to produce standards for such diagnostic tests.

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 other business was raised.

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

Special 2-Day JPAC meeting 20th and 21st November 2003 to be held at the Royal College of Obstetricians and Gynaecologists in London.