

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 25th Meeting held at Birmingham New Street Conference Suite on Friday 14th February 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 Virge James | (VJ) | - Chair, Joint UKBTS/NIBSC Professional Advisory Committee (Minute taker) |
| 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 Angela Robinson | (AER) | - Medical Director, National Blood Service |
| Mr Chris Turner | (CT) | - Medicines Control Agency |
| Prof. Stan Urbaniak | (SU) | - Standing Advisory Committee on Immunohaematology |
| Dr Keith Wilson | (KW) | - Welsh Blood Service |

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

| | | |
|----------------------|--------------|--|
| Dr Bruce Cuthbertson | (BC) | - Standing Advisory Committee on Plasma for Fractionation |
| Dr Stephen Inglis | (SI) | - Director, National Institute for Biological Standards and Control |
| Dr Tony Napier | (TN) | - Acting Medical Director, Welsh Blood Service |
| Mr Chris Rudge | (CR) | - Medical Director, UK Transplant |
| Miss C J Smith | (CJS) | - JPAC Secretary |

2. **MINUTES OF THE MEETING ON 10th October 2002**

- 2.1. The minutes of the last meeting held on 10th October 2002 were approved after the following amendment.

Page 7, item 9.1. Replace BBTS with BCSH.

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 3.4.** **Action**
- The Terms of Reference make this committee accountable to both the SAC on Blood Components and the SAC on Care and Selection of Donors; this should be reflected in the minutes.
- Action:** SM to inform Moji Gesinde. **SM**
- 3.2. **Non UK plasma – item 3.6. (point 1)**
- This item was not discussed at the UK Forum on 31st January 2003.
- Action:** Item to be put on the agenda of the next UK Forum Meeting in May. VJ to send a list of agenda items from JPAC. **VJ**
- 3.3. **Non UK plasma – item 3.6. (point 2)**
- AER informed JPAC that MSBT will not mandate the use of US FFP, but that this will come under the heading of “best clinical practice”.
- 3.4. **vCJD – item 3.8.**
- Action:** GG will write a letter to JPAC for comment, then send to SEAC. **GG**
- 3.5. **BCSH Guidelines on Hospital Blood Bank Computing – item 3.15.**
- PA will be asked to join the BCSH Working Group on this topic.
- 3.6. **Recommendations from the joint meeting on Granulocytes – item 7.6.**
- Medical Directors were requested to ensure that their Lead Clinicians are aware of this paper once SM has carried out the final changes. **SM & Medical Directors**
4. **EUROPEAN UNION DIRECTIVE 2002/98/EC**
- 4.1. AER informed JPAC that this Directive has now been published in the Official Journal of the European Union (L33, volume 46, 8 February 2003) and that the 4 Services had 2 years (plus 9 months grace) when the Directive will become operative in UK law. UK Government are to set up a body to develop a framework document for translating the Directive into Parliamentary law.
- CT informed JPAC that the MCA is likely to be one of the “Competent Bodies”. The role of the CPA, in respect of hospital transfusion laboratories, remains unclear, these may also come under MCA.
- Following discussion the meeting felt that JPAC had a responsibility to draw the attention of hospital transfusion laboratories to the EU Directive. Traceability is of particular concern.
- Actions:**
- NBS - AER will put on agenda of the National Hospital Transfusion Committee
 - SNBTS - IF will take to the User Group
 - WBS - KW to take to the BSQMG
 - NIBTS - MM will disseminate through the Regional System
 - MCA - CT will ensure communication with the MCA
- AER
IF
KW
MM
CT**

5. **REPORT TO THE UK FORUM – 31st January 2003** **Action**
- VJ requested Activity Reports and Forward Looks from all the SAC Chairs (including the Sub-Committees and Working Parties) by 1st May 2003, to enable her to compile a report for the UK Forum papers by 16th May 2003. **All SAC Chairs**
6. **FEEDBACK FROM THE UK FORUM – AER & IF**
- The discussions had centred on:
- 6.1. **Changes affecting the DoH, MSBT**
- Pat Troop has moved to become the Chief Executive of the Health Protection Agency.
- 6.2. **Position Statement on vCJD**
- UK Forum wish to ensure that anyone in the Services making comments on vCJD must ensure that their comments are consistent with the position statement.
- 6.3. **HBV Paper**
- This paper gives several options. The UK Forum requested SACTTI to state the preferred options. Option 4 outlines a study for which funding would be needed. No funding will be available from the UK Forum, but the NBS are undertaking a study under BTSAG.
- The paper is therefore not ready to take to MSBT.
- The paper was also planned for publication sometime so it could not go on the website as this would prejudice future publication.
- Following much discussion it was agreed that a position statement of current residual risk, of transfusion transmitted infection, should be prepared and placed on the website. Most of the data is available and can also be used in the PI Framework document.
- Action:** LL undertook for SACTTI to prepare this. **LL**
- BM asked that eventually this position statement is expanded to include all risks of transfusion. This was accepted but it was felt that this would take longer to prepare and the immediate need is for current TTI residual risk.
- Action:** BM to oversee expansion in future **BM**
- 6.4. **ISBT 128**
- The UK Forum has asked for a business case for the extension of ISBT labelling to component identification. Since this would entail much work it was felt that an assurance should be given by the UK Forum that serious consideration is being given to this extension. Currently the UK has implemented phase 1: donor and donation identification.
- Action:** PA to formulate letter. VJ to send to the UK Forum **PA & VJ**

6.5. **US FFP****Action**

This is expected to be available in the autumn of 2003. It was suggested that the use of this should be promulgated as best practice (as per MSBT). IF commented that unless this product is mandated it may not be used and he had serious misgivings about leaving the options open.

6.6. **Virtual Museum**

Virtual museum on the web is coming – IF initiative.

6.7. **Implementation Date of 6th Edition of Red Book**

Action: VJ to place 1st April 2003 implementation date for the 6th Edition of the Red Book on the website.

VJ**7. REPORT FROM JPAC WEBSITE**7.1. **HTML name change**

VJ informed the meeting that HTML has changed its name to “the driver is Ltd”.

7.2. **JPAC website and SHOT**

Following discussions with SHOT HTML had been asked to produce a proposal to host both JPAC and SHOT as independent sites but to see whether, as both were funded by the UK Forum any cost savings would result.

HTML was also asked to include in this a proposal for Donor Adverse Event Surveillance (DAES), and developing the JPAC resource site. This has been received.

There was discussion around all the 3 proposals separately:

- a) **SHOT**: PA felt that the SHOT site could be developed in the short term very speedily without HTML involvement, but this is a matter for SHOT. BM expressed the view that every encouragement should be given to SHOT to have a well run, fit for purpose site, particularly now in view of the haemovigilance demands of the EU Directive. This was supported.

Actions: VJ to discuss with Dorothy Stainsby. PA to advise on phase 1 – getting current SHOT site up and running.

VJ & PA

- b) **DAES**: the requirements for this may change with the proposals in the EU Directive and therefore the proposal needs to be redressed.

Action: VJ to discuss with Liz Caffrey and David Hutton

VJ

- c) **JPAC resource site**: this was not further discussed.

Ideally VJ would still like to take a proposal to the UK Forum. To be discussed at the Website Steering Group meeting on 16th April 2003.

7.3. **Implementation Issues****Action**

VJ again expressed concern that there were many issues in implementing the information available on the site, in particular the DSG.

AER commented that in the NBS there are designated Quality Managers for each Directorate.

Action: AER would take this further with them.

AER

The other Services did not seem to have the same problem as the NBS, possibly due to smaller size.

7.4. **Unrestricted access to DSG by May 2004**

It was formally agreed that JPAC supported the move towards unrestricted access to all DSGs. The aim was to achieve this by May 2004. It is also in keeping with the Freedom for Information Act

8. **SP-R-GS MEETING 4TH TO 7TH FEBRUARY 2003, SHEFFIELD**

VJ updated the meeting on the SP-R-GS meeting in Sheffield which was eminently successful.

The paper on Blood Pressure, submitted by SACCSO, was accepted and regarded as a model of how any future guideline changes should be represented to SP-R-GS, amassing all available evidence. The result is a change in wording in the 10th edition of the guide (2003) from: "It is recommended that Pulse and BP be measured ..." to "if Pulse and BP are taken,..."

The brief comments on pH of platelets were not considered to be sufficiently well presented to argue for a change to the guidelines. A paper is requested by November 2003 for discussion in February 2004.

Action: Paper therefore requested from SACBC by November 2003.

SM9. **HANDBOOK OF TRANSFUSION MEDICINE & E-LEARNING**

Handbook of Transfusion Medicine & E-learning was taken as a joint item with item 13 SACCTM.

There are still plans to attach an e-learning package to the Handbook on the website, but due to BM's absence these have fallen behind.

SU informed the meeting that Marion Scott was co-ordinating this for the BBTS, through the Professional Affairs and Education Committee of the BBTS.

Next joint meeting of SACCTM and BCSH is on October 14th. SU will attend.

KW asked for item 7, Minutes of the SACCTM meeting held on 14th November 2002 (JPAC Enc. 03/14), to be corrected with regard to Wales.

Action: KW to give correction to BM.

KW

10. **STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS** **Action**
- 10.1. **7-day platelets – JPAC Enc. 03/05 & JPAC Enc. 03/24**
- JPAC could only comment that SACBC were the group of experts who could decide what data was needed to sign off 7-day platelets. SM tabled JPAC Enc. 03/24 for information.
- Action:** SM to take to SACBC **SM**
- 10.2. **New Members**
- Dr Chris Prowse (SNBTS) - Secretary
 - Dr Lynn Manson (SNBTS)
 - Dr Khaled El-Ghariani (NBS, Sheffield Centre)
- 10.3. **Information regarding components on JPAC website**
- SM asked for permission to place information about all components, which have completed phase 0 validation, on the website: this was agreed.
- Action:** VJ and SM **VJ & SM**
- 10.4. **PI Framework**
- This document was sent to the UK Forum but not commented on.
- All aspects summarised in this framework document could not be included therefore it was felt that the UK Forum should indicate which particular areas they most wished to see completed.
- Actions:** SM to continue completion after EBA PI meeting in Dublin on 6th March 2003. **SM & VJ**
 VJ to send that version to Angus Macmillan Douglas and put on the agenda of the UK Forum meeting to be held on 23rd May 2003.
- 10.5. **Basic Life Support training for Apheresis Staff**
- Note the changes required to wording in the Red Book 6th Edition 4.3 and 4.6.
- Action:** VJ to prepare the concessionary letter before implementation date 1st April 2003. **VJ**
- 10.6. **NHSIA (NHS Information Authority)**
- PA has a full list of all components currently used. BM wondered whether for NHSIA a generic list rather than the numerous variations of the same components would be more helpful.
- SACIT Meetings with SACBC NHSIA to be taken forward.

11. **STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS** **Action**
- 11.1. **New Members**
- Dr Ellen McSweeney (Irish Blood Transfusion Service)
 - Dr Katie Davison (PHLS)
 - Dr Morag Ferguson takes the place of Dr Philip Minor (NIBSC)
- 11.2. **Evidence based Donor Selection Criteria**
- Paper expected in May 2003 for the June meeting of JPAC.
- 11.3. **Smallpox Vaccination – JPAC Enc. 03/25**
- Smallpox vaccination paper prepared by David Hutton JPAC Enc. 03/25 was tabled.
- Conclusion: 4 weeks for recipients of live vaccine was sufficient, but also a recommendation must be made about how to identify and defer household contacts.
- Action:** FB to progress rapidly.
- It was decided that the question of possible use of vaccinated people for production of antibodies should not be considered further as this was already commercially available
- FB**
- 11.4. **Donor Information sheets to support safety of blood leaflet**
- VJ updated the meeting on the progress of this. Currently final version is awaiting plain English translation and focus group testing. It has been decided that the final versions will appear on JPAC website, as this is a JPAC paper. All the 4 Services can then use the web version for producing their own with title of Service and appropriate service contact. Also Welsh translation.
- Action:** VJ. MM to send to Northern Ireland Equality Commission for information. **VJ & MM**
12. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**
- 12.1. **SACIH Key Issues**
- New member: Richard Stebbings, Immunobiology Department, NIBSC.
- Meeting next week. Main issue is the next Red Book, with the re-structuring to take account of the IVDA.
- One concern is how far the Red Book should go with advice to Hospitals. Any JPAC member with views should contact SU asap. Clair Milkins has been consulted on behalf of NEQAS, and invited as a new member of SACIH.
- IF requested clarification of the impact of the IV MD Directive on Red Book. It was felt that IVDA affected mainly manufacturers.

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

13.1. **SACIT Membership**

PA is still trying to identify a hospital consultant with interest in IT issues to serve on the SACIT, NTC IT Group.

13.2. **CMO National Transfusion Committee IT Group**

PA attended the first meeting of the CMO National Transfusion Committee IT Group. Issues discussed included:

- a) update on the work of SACIT
- b) UK Clinical Products Reference Source (UKCPRS) Project
- c) mapping the transfusion process (vein to vein)
- d) SNOMED-CT coding
- e) update on Bloodtrack and Safetrack pilot projects

13.3. **Hospital Computing Guidelines**

Transfusion Task Force has discussed the review of these guidelines.

13.4. **UK Blood Component Reference Table**

The project to create a master table of all component codes in use in the UK is approaching completion. New code requests are now channelled via SACBC and SACIT.

13.5. **Developing Technologies Meeting**

This special meeting was held in December 2002. Speakers from the Blood Service, suppliers and academia contributed. RFID and reduced space symbologies were the main items of discussion. There is the possibility of a piece of joint research being undertaken to review information transfer in the blood service.

13.6. **ICCBBA Middle East and Europe TAG**

PA had attended the recent meeting in Cairo. One of the issues that we need to be aware of is the adoption of symbols on blood pack base labels to replace text warnings/descriptions. It will be important to ensure awareness of this transition before it occurs.

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

Work on revising the chapter for the 7th edition is progressing.

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

15.1. **New Members**

Dr Sue Fuggle, Director of Clinical Transplant Immunology, Oxford Transplant Centre
Miss Sue Falvey, Director of Donor Care & Co-ordination, UK Transplant

- 15.2. **Working Party on Tissue Donor Consent** **Action**
- This paper was welcome, but everyone had not had a chance to read it and check compatibility with other documents on consent.
- Actions:** All read and send comments to VJ. This will then be prepared as a JPAC position statement on Consent for Tissues and will be posted on the web site. **All, VJ & GG**
- 15.3. **EU Directive on Tissues**
- There are several issues around this Directive.
- IF has written to MG.
(It was felt that the Directive would take a long time to reach fruition).
- Action:** GG to link with Peter Doyle (DoH). **GG**
- 15.4. **Adverse Reporting for Tissues**
- It is clear adverse event reporting both for patients and donors will be a requirement in the future.
- BATB wants a national reporting system for adverse events similar to SHOT. Needs to link to the NPSA.
- Action:** GG to prepare a paper for June 13th meeting of JPAC. **GG**
16. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION**
- 16.1. **Bacterial Contamination: Working Group to establish standards for arm cleansing, bacterial testing**
- Roger Eglin had agreed to lead this group but it has not yet been convened. This matter is considered urgent.
- Action:** LL to chase up **LL**
- 16.2. **HBVDNA/Anti HBC Pool Testing: Prevalence in donors**
- Roger Eglin and Paul Grant are drafting an NBS proposal. It is hoped that this will be available for the next SACTTI meeting on 11th March 2003. It is intended to make it available to JPAC.
- 16.3. **Extension of NAT Position Paper**
- It is understood that this is nearing completion. The draft has been promised for the SACTTI meeting in March 2003.
- 16.4. **Emerging Pathogens Position Paper**
- Brian McClelland had agreed to lead this but understandably the paper has been delayed due to his sick leave. A draft paper is now expected March 2003.

16.5. **Pathogen Reduction: Joint SACBC/SACTTI Paper****Action**

As discussed earlier Sheila MacLennan and Liz Love had discussed task allocation between the SACBC and SACTTI. They are now awaiting an update from the EBA Dublin meeting on 6th and 7th March 2003 before proceeding further.

16.6. **Archive Samples: Guidelines and Recommendations**

IF and Brian Dow are preparing this paper, a draft of which is expected in March 2003.

16.7. **HIV: SNBTS Incidence**

Data indicating an increase in HIV incidence amongst donors had been discussed at SACTTI and comparison made with recent data from England and Wales. At the same time the NBS had considered this matter in detail and prepared a number of papers dealing with the current position with respect to HIV combi testing and the introduction of HIV NAT in the SNBTS. This has resulted in a position paper and various briefing papers and background papers for the NBS Blood and Tissue Safety Assurance Group and the Executive.

16.8. **Parvovirus**

SACTTI had noted that the Health Council of the Netherlands have prepared a paper on blood products and Parvovirus B19 and this paper would be considered at the next meeting of SACTTI in March 2003.

16.9. **West Nile Virus**

It was noted that Chris Prowse had produced a Review for Transfusion Medicine. The WNV position will be discussed at the next SACTTI meeting in March 2003.

16.10 **CMV**

The production of a position paper on the merits of leucodepletion -v- sero negative components has been delayed but is still considered a priority on the SACTTI work programme.

17. **JOINT MEETING OF THE UKBTS/NIBSC SAC ON TISSUES AND STEM CELLS AND THE UKBTS/NIBSC SAC ON TRANSFUSION TRANSMITTED INFECTIONS**17.1. **Minutes of the meeting held on 12th November 2002**

LL pointed out that the Minutes had been issued with a number of typographical errors still present. These will be corrected and the revised minutes re-issued.

LL outlined a series of actions, which had been agreed at the joint meeting. The detail of these can be found in the Joint Meeting minutes and covered the following items:-

- Clinical Incident Panel and Tissues
- Testing for vCJD
- Bone risk assessment
- Risk assessment for other tissues
- Optimisation of microbiology testing
- Quarantine testing
- Export

Action

There were a number of actions on the SACTSC and the SACTTI which are still outstanding.

LL & GG

Action: LL and GG to follow up.

18. NIBSC

MF reported that NIBSC is actively progressing CE the Working standards used in the UKBTS for serological markers of infection.

Dr Charles Hunt has been appointed as Manager of the Stem Cell Bank at NIBSC and it is hoped that the final selection of contractor for construction of the building would be made by the end of February.

SI had agreed to look at the membership of the various sub-committees to refresh them. This had now been done and the following was suggested:

| <u>SAC</u> | <u>NIBSC Attendee</u> |
|------------------------------------|---|
| Blood Components: | Richard Stebbings no change |
| Care and Selection of Donors: | Morag Ferguson change from Phil Minor |
| Immunohaematology: | Paul Metcalfe no change |
| Plasma for Fractionation: | Trevor Barrowcliffe no change |
| Transfusion Transmitted Infection: | Sally Baylis change from Phil Minor, but with Phil continuing to cover the CJD subcommittee |
| Tissues and Stem Cells: | Charlie Hunt* change from Morag Ferguson |

19. ANY OTHER BUSINESS

19.1. MCA Inspections

CT: MCA inspections: No trends to report. He notes some concern that the increased storage requirements for emergency PODs could jeopardise GMP standards in some centres

GG asked what would be the position if all Tissue Banks have not achieved accreditation by March 2003 could they still issue tissues?

CT replied that the DoH is looking at the deadline. No answer so far.

PA reminded everyone of the consequences of freedom of information Act.

19.2. Chair of JPAC

VJ reminded the Medical Directors that she had hoped to introduce her successor to the UK Forum in May 2003, and indeed must introduce her successor to SP-R-GS in Feb 2004.

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

Thursday 12th June 2003 at the West End Donor Centre in London.