

Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 24th Meeting held at West End Donor Clinic, London on Thursday 10th October 2002

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 Bruce Cuthbertson	(BC)	- Standing Advisory Committee on Plasma for Fractionation
Prof. Ian Franklin	(IF)	- Medical Director, Scottish National Blood Transfusion Service
Dr Virge James	(VJ)	- Chair, Joint UKBTS/NIBSC Professional Advisory Committee (Minute taker)
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
Mr Chris Turner	(CT)	- Medicines Control Agency
Prof. Stan Urbaniak	(SU)	- Standing Advisory Committee on Immunohaematology

VJ welcomed Sheila MacLennan (new Chair of the SACBC), Chris Turner and Bruce Cuthbertson to their first JPAC meeting.

1. APOLOGIES Action

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 Liz Love	(LL)	- Standing Advisory Committee on Transfusion Transmitted Infection
Dr Angela Robinson	(AER)	- Medical Director, National Blood Service
Mr Chris Rudge	(CR)	- Medical Director, UK Transplant
Miss C J Smith	(CJS)	- JPAC Secretary

2. MINUTES OF THE MEETING ON 13th JUNE 2002

2.1. The minutes of the last meeting held on 13th June 2002 were approved after the following amendments.

Page 4. Remove reference to arrival of IF as agenda taken out of order
 Page 8, item 12. For not From
 Page 9, item 13.3. "any form of male homosexuality"
 Page 9, item 14.5. *T. cruzi*
 Page 5, item, 8.1. Should read **Donor** information leaflets

- | 3. | MATTERS ARISING FROM THE MINUTES OF THE LAST MEETING | <u>Action</u> |
|------|---|-----------------------|
| | Only matters not on the agenda are minuted in this section. | |
| 3.1. | <u>Handbook of Transfusion Medicine</u> – item 2.2. | |
| | Short statement about the official standing of the Handbook of Transfusion Medicine (as printed version), BCSH guidelines and web version of the Handbook of Transfusion Medicine is awaited. | BM |
| 3.2. | <u>New section on platelets</u> – item 3.4. | |
| | New platelet section is now in the 6 th Edition of the Red Book so will not appear on the website as a separate item. | |
| 3.3. | <u>Surplus Tissues</u> – item 3.5. | |
| | LL has put on the agenda of the Joint SACTSC and SACTTI meeting in November 2002. | |
| 3.4. | <u>Sub-Committee on Technical Aspects</u> – item 3.6. | |
| | FB informed JPAC that the Terms of Reference still need further amendment. Moji Gesinde has called a meeting in November 2002. | |
| | Action: VJ to speak to Moji Gesinde. | VJ |
| 3.5. | <u>In vitro diagnostics Medical Devices Directive</u> – item 3.7. | |
| | LL to ensure that the Working Party on Parasitology and Blood Safety is fully aware of this Directive. | |
| | Action: LL progressing. | LL |
| 3.6. | <u>Non UK plasma</u> – item 3.8. | |
| | IF requested that PA write to him outlining these concerns to take to UK Forum. Contracts are in preparation and some mention needs to be made about the relabelling issue. | PA |
| | IF requested clarification about the use of US FFP for children born after 31/12/95: is this compulsory or do clinicians and patients have discretion? Guidance from MSBT requested. | |
| | Action: AER and BM for next MSBT meeting in October 2002 | AER and
BM |
| 3.7. | <u>Donors who have suffered from depression</u> – item 3.9. | |
| | GG actioned. | GG |
| 3.8. | <u>vCJD</u> – item 3.10 | |
| | Actions still outstanding:
The CJD incident panel advice has been commented on. However, GG noted that for tissues it states that “Advice on exposure will be available at a later date”. | |
| | | <u>Action</u> |

GG to ask BM to see whether MSBT are considering this. **GG**

SACTSC to draft a questionnaire to be sent to orthopaedic surgeons explaining the proposals. Also contacting professional associations involved. GG progressing. **GG**

3.9. **Browser version of T-DSG – item 3.11.**

VJ is progressing. **VJ**

3.10. **Observers at JPAC – item 4.3.**

VJ has written to Prof. John Cash regarding an observer from the Irish Transfusion Service.

William Murphy is on the SACCTM and Ellen McSweeney has been invited as observer to SACCSD.

3.11. **Chair of SACBC – item 7.1.**

Dr Sheila MacLennan has been appointed.

3.12. **Donor Information Leaflet to support the Blood Safety Leaflet – item 8.1.**

FB and VJ updated the meeting: 2 supporting “information leaflet” drafts have been prepared by Kate Soldan. VJ has circulated these to the designated “writing group” (which she has been asked to chair).

The members are:

- Mr Eric Kay – Scottish LGBT Health Discussion Forum
- Dr Linda Lazarus – EAGA Secretariat at the DoH
- Dr Frank Boulton – Chair SACCSD, NBS
- Mr Chris Hartley – National Communications Manager, NBS
- Mr Nick Partridge – Terence Higgins Trust
- Dr Kate Soldan – NBS/PHLS.
- Representative from CRE (to be nominated)

VJ was asked to add Henry Hambley to the list to maintain direct communication with SNBTS. The aim is to complete the work by end of year. **VJ**

Action: VJ

3.13. **Member SACIT – item 11.1.**

Dr David Gozzard, Medical Director of Conwy and Denbighshire NHS Trust, was nominated

Action: PA **PA**

3.14. **ISBT 128 implementation – item 11.3.**

This matter had not been discussed at the last UK Forum meeting. IF asked PA to resubmit the briefing paper to him (copy to the other Medical Directors) for discussion at the next meeting of the UK Forum. **PA/IF**

Action: PA/IF

3.15. **BCSH Guidelines on Hospital Blood Bank Computing – item 11.4.**

FB reported that the issues raised have not yet been discussed by the Transfusion Task Force. He asked PA to resend all the correspondence and he will ensure it is discussed at the November Meeting.

Action: PA/FB

PA/FB

3.16. **T-DSG – Entry on organ donation/transplantation - Item 13.2.**

VJ to check with GG.

VJ

3.17. **Recommendation to re-define the UK Transfusion Microbiology Reference and Reporting Group as a permanent Sub-Committee of the SACTTI – item 14.6.**

VJ to see Marcela Contreras on Monday 14th October.

VJ

3.18. **Malaria - Item 16.3.**

No information. Action: VJ to check.

VJ

3.19. **European Haemovigilance Network (EHN) and SHOT – item 17.2.**

No information. Action: VJ to check.

VJ

4. **“RED BOOK” ADMINISTRATION**

4.1. **JPAC Report – JPAC Enc. 02/36**

JPAC report accepted.

4.2. **Website**

There is a meeting at HTML on Friday 11th October 2002 where the progress of the website will be discussed. VJ will report back to JPAC and the UK Forum

VJ

5. **REPORT FROM THE UK FORUM MEETING 26TH JULY 2002**

IF reported the following discussions:

- **EU Directive**

The wording causing concern has been changed indicating that all donors do not need to be seen at a session by a medically qualified person prior to donation, but the whole process will be under the direction of medically qualified staff.

The preparation of the technical appendices to the Directive is progressing and the UK and EBA will have input.

- **DoH and HCV NAT Contracts**

Discussions with the DoH regarding HCV NAT contracts are ongoing.

- **Bacterial Reduction**

Discussion took place on bacterial reduction. Whilst the paper submitted from JPAC to the UK Forum had not been totally clear it was accepted that JPAC was the definitive advice giving body (see also SACTTI report).

- **New Consultant Contract**

The possible consequences of the new consultant contract and the effect on JPAC membership.

- **EU Tissue Directive**

An EU Tissue Directive on tissue transplantation is in preparation, and a future one on tissue engineering is under discussion. (Information from Chris Turner)

- **UK Forum Meeting 8th November 2002**

JPAC will be submitting 5 papers:

- Paper on pathogen inactivation (SACTTI)
- vCJD Position Statement (SACTTI)
- Report on progress on SACCSO paper on donor selection criteria
- Report on the progress with setting the standards for reduction of bacterial contamination
- The HBV paper and recommendations

VJ will also submit an update on the website.

6. **RED BOOK 6TH EDITION**

VJ reported that publication is still on target for November and reminded all chairs to start preparing their contributions for the 7th edition. The aim is to bring the publication date in the year forward to at least April so the contributions should be in by early January 2004 to allow publication in April/May 2004. Totally revised chapters are expected from Quality and SACTTI.

**All SAC
Chairs**

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

7.1. **Resignation of the Secretary of SACBC**

Martin Bruce has tendered his resignation after many years of invaluable service on SACBC. The meeting records formal thanks to him.

7.2. **pH of apheresis platelets**

The CoE currently gives pH values in the range of 6.8-7.4 at the end of shelf life. SACBC has stated that the UK cannot meet these values and the pH should be extended to 6.4-7.4. VJ has been asked by CoE for the evidence for this change request and SM will now undertake to prepare a short paper for VJ to take to the CoE by November 2002 for the meeting in Feb 2003. If this is accepted then a change to the CoE guidelines will happen, if not, the recommendation will remain as it is and the UK will not be able to meet this particular specification.

SM

7.3. **Imported plasma for FFP**

SACBC would like to see a specification whereby plasma is obtained from non-transfused male donors (for reduction of TRALI). This is unlikely to be feasible due to procurement difficulties.

7.4. **Overnight hold of plasma**

The Technical Committee is looking at overnight hold to increase yield.

7.5. **Framework for evaluation of pathogen inactivation of blood components – JPAC Enc. 02/54**

This framework paper, (requested by the UK Forum) was accepted as a most valuable summary of the current position. Following a few amendments by BM, including some assessment of the robustness of the claims made for the processes, it will go to the UK Forum for their meeting on 8th November 2002.

BM/VJ

7.6. **Recommendations from the Joint meeting on Granulocytes – JPAC Enc. 02/55**

Final Recommendation: this was accepted (change required from UKTS to UKBTS to avoid confusion with UK Transplant Services) and will be incorporated into the next editions of the guidelines. It will also be distributed to clinicians throughout the 4 Services as the JPAC advice.

Action: SM to carry out final changes and MDs to forward to their relevant clinicians.

SM/MDs

8. **STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS**8.1. **Human Rights – JPAC Enc. 02/40**

JPAC endorsed the SAC view that all donors have a right to a clear explanation of reasons for deferral / exclusion.

Action: FB to include in Chapter for next edition of Red Book.

FB

8.2. **Review of Donor Selection Criteria – JPAC Enc. 02/42**

JPAC congratulated FB and the SAC on a very clear and thoughtful document. This will now become the basis for further work for a paper to UK Forum which should include some data on numbers of donations saved and also some guidance as to which criteria are the most likely to yield the greatest numbers of donations saved. The paper therefore will not go to UK Forum this November but the SAC were asked to prepare a document for the next UK Forum meeting (probably February 2003).

Action: FB

FB

8.3. **DAES**

This is progressing. David Hutton is working closely with Nicky Anderson (NBS) to collect data on available databases. Once clear definitions have been agreed by the SAC and JPAC on “ serious “ events then the possibilities of collecting this information via the JPAC website to enable all 4 Services to input easily will be further discussed.

Action: FB.

FB

8.4. **DAT positive donors**

The Red Book 6th Edition states “Donors whose DAT remains positive for more than one year should be removed from the donor register and referred to their GP.”

FB

9. **STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE**9.1. **Joint meeting of the SACCTM and BBTS Transfusion Task Force**

There will be a joint meeting of the SACCTM and the BCSH Transfusion task force on November 14th to:

BM

- identify areas for Handbook inclusion from new BCSH guidelines in preparation
- look at the areas which need radical revision (ex; blood administration)
- Liaise with planned systematic reviews

9.2. **Handbook of Transfusion Medicine**

The current aim is for a revision of the handbook by mid 2003. As the TSO has been generally unhelpful in meeting our requirements (website access / revision facilities) a new publisher may be sought. There will be issues about finance to be addressed soon.

VJ

9.3. **DoH Better Blood Transfusion web area**

There is some concern that the DoH Better Blood Transfusion web area is not easy to find, nor would it be a natural area for people seeking advice to look and it is felt that one site in the UK which concentrates on BBT would be helpful to promote the message. Currently our site would be the preferred option. Discussions are ongoing with DoH as to how best to develop their and our site and establish appropriate links.

Action: BM & VJ

BM/VJ

10. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

10.1. The Terms of References for the Working Party on Donation Testing and the Working Party on Red Cell Reagents, tabled by SU, were accepted by JPAC.

10.2. **Indemnity when replying to website queries**

Clarification still awaited.

VJ

11. **STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY**11.1. **Labelling of autologous donations.**

There are issues around the labelling of these donations both from the supplier (BTSS) and the user (Hospital) end. ISBT does allow for such labelling. Following discussion, and bearing in mind that we collect not only autologous red cells

but also granulocytes and stem cells, PA was asked to extend the ISBT codes for autologous and also directed donations. Looking to the future autologous and crossover was also included.

PA

12. **STANDING ADVISORY COMMITTEE ON PLASMA FROM FRACTIONATION**

Work on revising the chapter for the 7th edition is progressing. Anti-D content of plasma, virus inactivation, NIBSC standards are all issues to consider.

BC

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

13.1. **Membership**

Phil Yates will join the SACTSC.

13.2. **Working Party on Tissue Donor Consent**

The group has finished its deliberations and a draft paper is currently in circulation it should be ready for the next JPAC meeting on 14th February 2003.

13.3. **Human Tissues Human Choices**

GG has responded to the consultation document "Human Tissues, Human Choices" on behalf of SACTSC.

Action: GG to send copy of response to VJ for "archive".

VJ

13.4. **Joint SACTSC and SACTTI Meeting**

Arrangements for the Joint SACTSC and SACTTI meeting in Manchester on 12th November are progressing well.

GG/LL

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

IF reported key issues.

14.1. **Transfusion Transmitted Hepatitis B Virus (TT-HBV) discussion paper on policies to reduce TT-HBV – JPAC Enc. 02/52**

JPAC accepted this paper which is also being prepared for publication by Kate Soldan. The paper recommends further research and VJ was requested to send the paper to UK Forum and also R&D Directorate of the NBS as this will require funding. As this paper is being prepared for publication we cannot at the moment release it for our website.

14.2. **vCJD Position Statement**

Accepted by JPAC and will appear on website as soon as possible with the addition that there will be a review whenever new information comes to light but at least annually.

VJ

14.3. **West Nile Virus**

At the moment not causing concern in UK but situation is being monitored.

14.4. **HIV**

Following years of decline in HIV positive donors there are now sharp increases in SNBTS and NIBTS. HIV NAT has been a low priority but this situation may need to be reconsidered. Action: LL for SACTTI

LL

14.5. **Storage of archive samples**

Paper in preparation.

14.6. **Bacterial Contamination**

Roger Eglin has set up a Working Party to consider the standards. There will also be an NBS workshop on October 25th which will feed into the RE WP

LL

14.7. **Kate Soldan**

Kate Soldan has now left the NBS and PHLs and taken a post in France. She has been an invaluable contributor to the work of JPAC both on SACCSD and SACTTI and we wish to record our formal thanks.

VJ

15. **NIBSC**

No items were submitted.

16. **UKT**

Following discussions at the UK Forum VJ has written to CR suggesting the following membership: Sue Sutherland on UK Forum, CR on JPAC and a transplant co-ordinator to join SACTSC. A nomination will soon be forthcoming from UKT.

17. **MCA**

CT explained the current merger of MCA and MDA as the new Medicine and Health Care Products Regulatory Agency. Further information will be forthcoming in due course.

The process of inspecting Tissue Banks has started and so far 10 have been accredited. 45 applications are outstanding. Training of inspectors is in progress

18. **ANY OTHER BUSINESS**

18.1. **Granulocytes**

SM reported that Derwood Pamphilon felt it was not necessary to provide a list of "experts" as consultants at Centres were able to hand these requests.

18.2. **Consequences of widespread smallpox vaccination**

FB drew the attention of the committee to the possible consequences on donations of

widespread smallpox vaccination since this would impose a deferral period of 4 weeks
He was asked to prepare a paper for UK Forum and draw their attention to this issue.

FB

18.3. **Deferral of transfused donors**

BM stated that there is an MSBT meeting imminent (22nd October 2002) where the issue of deferral of transfused donors will once again be discussed.

18.4. **SHOT Co-ordinator**

Dorothy Stainsby has been appointed to the post of SHOT Co-ordinator. VJ to send her JPAC congratulations

VJ

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

Following discussion the date of the next meeting in February has been changed from 13th February to **Friday 14th February 2003**. Venue to be advised.