Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 28th Meeting held at NBS Birmingham New Street Conference Suite on Wednesday 18th February 2004

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 Richard Jones	**(RJ)**	-	Medical Director, Welsh Blood Service
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 and Healthcare Products Regulatory Agency
Prof. Stan Urbaniak	**(SU)**	-	Standing Advisory Committee on Immunohaematology
Miss Caroline J Smith	**(CJS)**	-	JPAC Secretary

GUEST

Dr Rachel Green	**(RG)**	-	Scottish National Blood Transfusion Service

VJ welcomed Dick Jones to his first JPAC meeting as Medical Director for the Welsh Blood Service.

1. APOLOGIES **Action**

Dr Bruce Cuthbertson	**(BC)**	-	Standing Advisory Committee on Plasma for Fractionation
Mr Chris Rudge	**(CR)**	-	Medical Director, UK Transplant

2. MINUTES OF THE MEETING ON 21st NOVEMBER 2003

The minutes of the last meeting held on 21st November 2003 were approved with two corrections.

- Item 3.3. should read “Accreditation of Tissue Banks has been extended to March 2004”.
- Item 4. should read “Richard Gutowski is the DoH Representative”.

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

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

3.1. **EU Directive – item 4**

AER updated JPAC on the EU Directive.

- AER confirmed it will be law in the United Kingdom from 8th February 2005.
- Guidance must be available 3 months before it becomes law.
- Richard Gutowski will be giving a series of seminars around the Country. Tom Kelly has been seconded to assist Richard Gutowski in the "transposition" process.
- Blood Banks will need to be licensed and inspected, but an inspecting organisation has not been identified.
- Serious Adverse Event Reporting – this has to happen but the mechanism is not yet clear.

3.2. **Discussions with MHRA re IVD Directive – item 5 (JPAC Enc. 04/22 and 04/23)**

VJ tabled JPAC Enc. 04/22 (e-mail from Richard Bedford – Discussions with MHRA re IVD Directive) and JPAC Enc. 04/23 (letter from Richard Bedford to Bruce Cuthbertson).
AER stated that the NBS is a legal entity, the other UK Services need to check their status.

3.3. **Article for Transfusion Today – item 7**

VJ to progress.

3.4. **Red Book User Questionnaire – item 8.1.**

A follow-up survey will take place in the future.

3.5. **pH of Platelet Concentrates – item.3.**

Closed.

3.6. **Safety of Blood Leaflets – item 10.1.**

Inclusion of HTLV positive donors in deferral criteria - FB to prepare the additional information and inform all the 4 Services, including Tissue Services. **FB**

3.7. **Liability – sending Tissues outside the UK – item 15.4.**

GG is collecting data and will write to AER. **GG**

3.8. **SEAC – item 15.2.**

The next SEAC meeting is taking place on 25th February 2004 and will discuss risk assessment of both bones and tissues. This will also be discussed at the MSBT meeting on 11th March 2004.

GG emphasised the importance of consultation with users prior to papers being public. MSBT is expected to lead the consultation.

3.9. **Calculated Microbial Risk from Blood Transfusion – item 16.2.** **Action**

SACTTI will look at risk again in March 2004 – there appears to have been an increase in residual risk of HIV, but it is not clear if this reaches statistical significance. SACTTI to gather information together to provide a range for the UK. JPAC is keen to post a set of residual risk data. **LL**

3.10. **SACTTI Position Statement: CMV Seronegative vs leucodepleted blood components – item 16.7.**

This paper was presented at the previous JPAC meeting. FB commented that it would be useful to feed into the development of BCSH guidelines. FB will write to the Medical Directors of the 4 Services to ask for help with writing these. **FB**

3.11. **Position Statement: NAT Testing**

SACTTI will incorporate aspects of this paper into the one being developed on emerging pathogens. **LL**

3.12. **Links with Health Protection Agency – item 5.2.**

HPA links with JPAC need to be bi-lateral and formal.

GG informed the meeting that he will be attending a HPA meeting on Microscreening of Tissues Cells and Organs on 23rd February 2004. SACTTI to send papers to GG. LL has asked Steven Dobra at EOR to help with mapping links. **LL**

4. UK FORUM

IF and AER reported back from the UK Forum meeting on 6th February 2004.

Main items discussed were:

- Review of MSBT
- Previously transfused donors.
- Need to modify patient information leaflet.
- EU Directive
- SHOT
- TRALI
- Dorothy Stainsby, Virge James and Brian McClelland to be invited to the next UK Forum meeting.

MM

Morris McClelland was asked to consider circulation of UK Forum minutes to the Chair of JPAC.

5. REPORT FROM THE CoE SP-R-GS MEETING - DUBLIN 3rd to 6th February 2004 (JPAC Enc. 04.01)

VJ elaborated on her report JPAC Enc. 04/01.

5.1. **Malaria**

Malaria is still an issue where there is confusion and the CoE have asked the UK to contribute to formulating guidance and make National Blood Service MAT test results available. **BM**

6. **EUROPEAN UNION DIRECTIVE** **Action**

Discussed under item 3.

7. **JPAC ISSUES**

7.1 **New Chair of JPAC**

Brian McClelland takes up the JPAC Chair from 1st May 2004.

7.2. **7th Edition of the Red Book**

VJ is working with BM to bring out the 7th Edition of the Red Book by late 2004. All contributions must reach VJ by the end of March 2004.

7.3. **Website update**

VJ updated JPAC on changes to the website.

- The launch of the current guidelines in CMS format is due to take place on 1st March 2004.
- The JPAC Resource area will be launched on 1st April 2004.
- The launch of the DSG with new changes is planned for June 2004. FB to bring changes to JPAC first. **FB**

Hosting of the NBS Blood Conservation Strategy on the website was discussed. JPAC felt that this is not the appropriate site to host this document, but JPAC could link to it on either the NBS or BBT sites. BM to discuss with Denise O'Shaughnessy from the Department of Health. **BM**

8. **SUPPLEMENTARY INFORMATION SHEETS TO THE SAFETY OF BLOOD LEAFLET**

8.1. **Report of the Writing Group to Draft Supplementary Information Sheets to the Safety of Blood Leaflet to JPAC - JPAC Enc. 04/02a and 04/02b**

VJ listed the agreed next steps:

- Translate into Welsh
- then host on JPAC website – it is aimed only for people requesting further information NOT for general distribution.

Chris Hartley NBS and Barbara Handcock WBS to liaise.

9. **MICROBIOLOGICAL SAFETY OF BLOOD AND TISSUES (MSBT)**

The reorganisation of MSBT has been delayed. JPAC will send their views on the previously circulated discussion paper. **BM**

10. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS **Action**

10.1. **Proforma for the capture of donation and processing data for bacterially contaminated units – JPAC Enc. 04/04** **MDs**

MDs to take back for their QA Managers to implement in their Services.

10.2. **Maximum storage time of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP – JPAC Enc. 04/05**

JPAC to issue concessionary letter extending shelf-life to 24 months. **VJ**

10.3. **Framework for evaluation of pathogen reduction of blood components (updated version) – JPAC Enc. 04/06**

This paper has been requested by the UK Forum. LL and SM to update the paper again and send to BM to send to the UK Forum. **LL & SM**

10.4. **Extension of post-thaw shelf life of FFP (7.14 Fresh Frozen Plasma) - JPAC Enc. 04/07**

- Section 7.14 was endorsed by JPAC.

10.5. **Database of evaluations in UK Blood Services for SACBC TG - JPAC Enc. 04/08 and Note of explanation to go with table of evaluations - JPAC Enc. 04/09**

BM

It was agreed that this would be hosted in the JPAC Resource area of the website.

10.6. **Leucodepletion Residual Risk – JPAC Enc. 04/10**

SM was requested to revise this paper including levels of residual risk of CMV. May need statistical input. **SM**

10.7. **Labeling of RhD group of FFP**

- BM requested a paper from SM and SU to bring back to next JPAC meeting. **SM & SU**
- SM and SU to get data and take to the Council of Europe via AER – EBA and EU. **SM & SU**
- FB will seek SU's views for BCSH. **FB**
- BM to send evidence to the CoE for the next edition of the "Guide to the preparation, use and quality assurance of blood components". **BM**

11. STANDING ADVISORY COMMITTEE ON TISSUES AND STEM CELLS

11.1. The next SAC TSC meeting at the beginning of March 2004, will review DSG guidelines. The Microbiology Testing of Tissue and Stem Cell Donors Group has met once and will report back at the JPAC meeting in June. **LL**

11.2. **CoE "Guide to the safety and quality assurance for organs tissues and cells"**

Rachel Green reported back from the CoE group producing the second edition of the "Guide to the safety and quality assurance of organs tissues and cells".

- A meeting took place in June 2003 - they follow a similar process to the SP-R-GS. **Action**
- Main changes are in the Chapter on Quality.
- There is very little information which is not in the Red Book.
- The group are about to review comments on the second draft.

Rachel Green will send a copy of the draft to CJS to circulate to JPAC for information. **RG**

11.3. **TEARS (Tissue Event and Adverse Reaction Scheme) Steering Group, Terms of Reference – JPAC Enc. 04/16**

GG presented this paper and there was much discussion. It is generally agreed that a system for reporting adverse events and reactions for tissues, similar to SHOT, will be required.

There are several concerns:

- Will this be a formal reporting system as probably required by the EU Directive on tissues? If so there are the same issues as for blood components.
- Is this an informal system like SHOT? In which case definitions need to be agreed.

GG was asked to take these considerations back to the steering group. If a system similar to SHOT is envisaged funding will be requested from the UK Forum. **GG**

12. STANDING ADVISORY COMMITTEE ON CARE AND SELECTION OF DONORS

12.1. **Donor Selection Criteria**

FB stated that the SACCSD were still working though the list of donor selection criteria – no progress report. There is a clear need for this much awaited report. **FB**

12.2. **vCJD and transfusion donor exclusions**

This was discussed at length.

- Concern that blood transfusion may be a vector for vCJD transmission has led to the additional precaution of deferring previously transfused donors.
- In relation to the risk from the food chain pre 1996 the additional risk of having received blood is difficult to quantify. At present, it is likely to be low.
- Reducing the risk of any additional way of developing vCJD is important as a public health measure, but no figure as to the degree of risk reduction is available.
- Ceasing to accept previously transfused donors will have an overall impact on safety, based on MSBT data.
- Risk to patients exists in a lack of supply. This is especially so for platelets. Tissue donors would also be affected disproportionately.
- The prudent course of action is to implement this safety measure over time to minimise known risks to patients from lack of platelets and red cells. This was done for UK plasma deferral, for the introduction of leucodepletion and for importation of US fresh frozen plasma for children born after 31.12.95.
- It was noted that JPAC had not been involved with this issue prior to the DoH announcement.

12.3. **Haemoglobin Levels** **Action**

Following a meeting with Richard Gutowski on transposing the Commission Directive AER has asked FB to prepare a paper on all the evidence he produced allowing the UK to lower the Hb levels for donors. **FB**

13. STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE

13.1. **Handbook of Transfusion Medicine**

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

- Production of the next edition is in progress.
- There will be a change of emphasis to good blood management.
- Relationship between guidelines and quality of the evidence.
- It is hoped that the next version will also be available in CD format.

14. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

SU informed JPAC that assessing the impact of the IV Directive is ongoing.

15. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

15.1. PA updated JPAC on SACIT key issues:

- Component Code Mapping Group is progressing well.
- Autologous Labelling - PA to circulate text to SAC chairs and would appreciate feedback.
- Group on Stem Cell Labelling has met twice. **PA**

15.2. **Tissue Banking ISBT 128 labelling**

DoH very supportive and there is good buy in from the BATB and Cornea people. Working with Deirdre Fehily in Italy regarding EC technical annexe on Coding Systems. There is some concern that the EC could try to mandate a bar-coding system in for blood components.

15.3 **BCSH guidelines on Hospital Blood Bank Computing**

The BCSH guidelines on Hospital Blood Bank Computing are in revision and will include reference to the EU Directive requirements.

15.4 **National Transfusion Committee IT Sub Group**

This group was set up at the beginning of the year, sitting under the Chief Medical Officers National Transfusion Committee, to look at IT issues.

16. STANDING ADVISORY COMMITTEE ON PLASMA FOR FRACTIONATION

Phil Minor is on the EU Biotechnology group and can be consulted. **VJ & BM**

17. **STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION** **Action**

LL reported back to JPAC on the following SACTTI issues:

- SACTTI will reconsider WNV – Roger Eglin has produced a paper which will be put to SACTTI. LL informed JPAC that the French are to study testing for WNV in Southern France this summer.
- HIV risk assessment - awaiting update.
- Leishmaniasis – work is still in progress.
- Malaria risk in Iraq – malaria risk area might be extended. More work on this paper is needed. FB has had a request from the Army for information and a paper from SACTTI would be very useful. **LL**

18. **Items raised by NIBSC**

No items were raised.

19. **Items raised by MHRA**

19.1. **Accreditation Scheme**

110 Tissue Bank sites have applied for accreditation and the MHRA have accredited 40 to 50 sites. DoH are aware of the issue.

19.2. **i/v fibrinogen**

It is suggested that direct contact is made with the MHRA over this issue. CT to send name of a contact at the MHRA to VJ. **CT & BM**

20. **Items raised by UK Transplant**

No items were raised.

21. **ANY OTHER BUSINESS**

21.1. **Chris Turner**

Chris Turner is leaving the MHRA and this therefore would be his last meeting. JPAC thanked CT for his input to the group.

Virge James

21.2.

Virge James will be retiring from the National Blood Service in May 2004 and this is therefore her last meeting as Chair of JPAC. JPAC thanked Virge for all her hard work over the last 6 years as Chair of JPAC.

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

Thursday 17th June 2004 at the Novartis Foundation in London.