Joint UKBTS/NIBSC Professional Advisory Committee

Minutes of the 21st Meeting held at the West End Donor Centre, London on Thursday 11th October 2001

Meeting commenced at 11.00 am

PRESENT

Dr Frank Boulton (FB) -Standing Advisory Committee on Care and Selection of Donors

Dr George Galea (GG) -Standing Advisory Committee on Tissue Banking

Dr Virge James Chair, JPAC (VJ) -

Standing Advisory Committee on Transfusion Transmitted Infection Dr Brian Dow (BD) -

(attending for Dr Liz Love)

Standing Advisory Committee on Clinical Transfusion Medicine Dr Brian McClelland (BM) -Dr Morris McClelland (MM) -Medical Director, Northern Ireland Blood Transfusion Service

Dr Morag Ferguson (MF) -National Institute of Biological Standards and Control

Dr Angela Robinson (AER) -Medical Director, National Blood Service

Dr Lorna Williamson (LW) - Standing Advisory Committee on Blood Components

IN ATTENDANCE

Miss Caroline J Smith (CJS) - Secretary

Virge James welcomed Brian Dow to the Group who was attending for the SACTTI.

1. <u>APOLOGIES</u>

Apologies were received from:

Mr Paul Ashford	(PA)	-	Standing Advisory Committee on Information Technology
Dr Bruce Cuthbertson	(BC)	-	Standing Advisory Committee on Plasma for Fractionation
Prof Ian Franklin	(IF)	-	Medical Director, Scottish National Blood Transfusion Service
Dr Mike Kavanagh	(MK)	-	Medicines Control Agency
Dr Liz Love	(LL)	-	Standing Advisory Committee on Transfusion Transmitted Infection

Acting Medical Director, Welsh Blood Service Dr Tony Napier (AN) -Dr Peter Phillips (PP) - National Institute of Biological Standards and Control

(GS) - National Institute of Biological Standards and Control Dr Geoffrev Schild Prof Stan Urbaniak (SU) - Standing Advisory Committee on Immunohaematology

MINUTES OF 20th MEETING HELD ON 14TH JUNE 2001 2.

ACTION

The minutes were accepted and approved.

Morag Ferguson and Morris McClelland arrived at the meeting.

3. **MATTERS ARISING**

ACTION

3.1. Council of Europe Guidelines "Guide to the preparation, use and quality assurance of blood components" 8th Edition - Consultative phase - item 3.2.

VJ informed the JPAC that comments had been received from the SAC Chairs, collated, and sent to AER on 24th July 2001.

3.2. Attendance of Chair of JPAC at SAC meetings - item 3.3.

VJ had now attended one meeting of most of the SACs.

3.4. Membership of SACs - item 3.4.

Membership lists of some SACs have still not been received. Chairs, who had not already done so, were asked to send details of their membership to VJ.

3.5. **Indemnity - item 3.4.**

Clarification on indemnity was still required. VJ had written to Mr Stephen Janisch, of Le Brasseur Tickle, formally on behalf of the JPAC regarding liability for professionals working in the National Health Service. A reply is awaited.

3.6. Labelling for patient notes - item 3.7.

LW informed the JPAC that the Transfusion Task Force of the BCSH were not planning to write anything on this subject. Paul Ashford was corresponding with Paul Kelsey on this matter.

FB agreed to take forward on behalf of JPAC.

FB

GG

ALL

VJ

3.7. CoE draft "Guide on Safety and Quality Assurance for Organs, Tissues and Cells" - item 3.8.

Copy of the formal response to the CoE document, for the "Red Book" archives, is still awaited.

3.8. Reinstatement of donors who have false positive screening tests (JELC Enc. 01/31) - item 3.10.

AER informed the JPAC that LL had written to Roger Eglin on her behalf.

3.9. **EDI messaging - Membership of HL7-UK - item 11.3.**

VJ informed the JPAC, on PA's behalf, that he and Ian Harris had attended a meeting of HL7-UK as guests and that the meeting was very informative. He would therefore proceed with the membership application.

3.10. Membership of SAC on Information Technology - item 11.4.

VJ informed the JPAC, on PA's behalf, that the SAC on Information Technology currently has 2 medical representatives - Dr Phil Yates a Consultant Haematologist from a Blood Service background and Dr Jonathan Wallis, a Hospital Consultant Haematologist.

ACTION

PA had previously notified VJ of Richard Bedford's resignation from the SACIT and asked VJ to ask JPAC for any suggestions for a replacement who could give input from a Blood Service operational perspective.

ALL

3.11. Japanese translation of the "Red Book" - item 16.2.

On advice from TSO, VJ had written to Dr Ryushi Shimoyama to informed him that he needed to write to Her Majesty's Stationery Office (HMSO), for permission to translate the "Red Book", as it is a Crown Copyright publication.

3.12. Ethics Committee - Discussed mainly under item 6.3.

In the absence of IF AER agreed to clarify and report back to JPAC.

AER

3.13. DoH Clinical Incident Advisory Panel on vCJD

AER informed the JPAC that a press release was imminent. Advice had gone out to consultation before the next meeting of the Incident Panel on 18th October 2001. Letters will be produced giving advice to people who make enquiries.

LW felt that this would be a good time to develop, with hospital pharmacies, better systems for tracking recipients of fractioned plasma products.

AER to take to UK Forum.

AER

4. "RED BOOK" ADMINISTRATION

4.1 **New Chairs**

Virge James informed the JPAC that Prof Stan Urbaniak had been appointed to Chair of the Standing Advisory Committee on Immunohaematology.

4.2. "Red Book" 5th Edition

4.2.1. Distribution of the 5th Edition of the "Red Book"

VJ informed JPAC that the 5th Edition (2001) had been sent to the 4 Services in mid September for onward distribution.

4.2.2. Electronic Version of the 5th Edition of the "Red Book"

The electronic version had appeared on the TSO website since mid August and was also accessible through the NBS Intranet, under UK Medical Guidelines in the MED (Medical) section. The other Services with Intranets should have similar access.

4.2.3. Proof Reading of Chapters

The JPAC agreed that for future editions of the "Red Book" SAC Chairs would be asked to proof read their own Chapters. Very little time is allowed for this, so speedy returns will be required. LW mentioned that she had heard rumours that a section on Platelets

LW mentioned that she had heard rumours that a section on Platelets had been left out of the "Red Book". VJ will look into this matter.

ACTION V.J VJ agreed to circulate editing instruction to SAC Chairs before the next revision.

٧J

VJ informed the JPAC that the TSO had not produced a copy of the 5th Edition of the "Red Book" in "Word" format.

4.2.4. Implementation "Red Book"/UK Forum

VJ informed the JPAC that she was awaiting "implementation" dates from the Medical Directors.

In the meantime the following notice appears on the TSO website:

"The 5th edition replaces the 4th edition as a working document on the following date.....". VJ has agreed the wording with MK.

4.3. Website Progress - JPAC Enc. 01/61

4.3.1. Design ideas for website

VJ tabled JPAC Enc. 01/61 which showed three draft colour printouts from HTML of the design ideas for the website and after discussion the following were agreed by JPAC:

- Homepage Graphical style was accepted as long as the graphics don't make loading the homepage too slow.
- Title UK Blood Transfusion and Tissue Transplantation Guidelines.
- Domain name transfusionguidelines.org.uk or transfusionguidelines.org - all one word or an underscore between transfusion and guidelines if the names are not available.
- Access unrestricted access to both the "Red Book" and the Handbook of Transfusion Medicine

JPAC requested that the website should state that the Handbook of Transfusion Medicine was a "living" document including new/additional information. The official version is the published version as printed and accessed on the TSO website.

4.3.2. Next meeting with HTML

A meeting between VJ, PA, Serge Six, Nicky Anderson, Tim Wallington and HTML was taking place on 23rd November. VJ requested that BM attend this meeting and he accepted. CJS to forward details of this meeting to BM.

CJS

4.3.3. Cost of website

ACTION

VJ informed the JPAC that the initial cost of setting up the website was approx. £19,000. It will cost approx. £1,000/year to maintain and

£40/hour for any changes.

4.3.4. <u>Donor Selection Guidelines (DSG)/Tissue Donor Selection</u> <u>Guidelines(T-DSG) - restrictions</u>

It was agreed that these should remain restricted documents. VJ requested that FB, for DSG, and GG for T-DSG, give her a list of who these guidelines should be restricted to. These and any other comments by JPAC members should be sent to VJ before 23rd November 2001.

FB & GG

BM suggested that, in the long-term, the objective should be to have open access to these documents.

4.4. Donor Selection Guidelines - Implementation Dates

Difficulties were being experienced regarding the implementation dates of these guidelines and this still needs to be resolved.

AER requested that if we have to make a concessionary change it should appear on the webpage and still be routed through the JPAC office and Medical Directors.

4.5. Update on the "Red Book" committee structure - JPAC Enc. 01/60

VJ tabled JPAC Enc. 01/60 the organisation structure of the committee in October 2001.

4.5.1. Structure of the SAC on Tissue Banking - JPAC Enc. 01/62

GG tabled JPAC Enc. 01/62.

GG stated that the SAC on Tissue Banking wished to change the name of their SAC to "Standing Advisory Committee on Tissues and Stem Cells". The JPAC agreed to this change.

The JPAC also agreed to the setting-up of two sub-committees, 1 on tissues and 1 on stem cells. It was re-affirmed that sub-committees are permanent and working groups are ad-hoc.

LW raised the issue about the amount of time spent by SACs in annual review of the "Red Book", CoE and EU guides. This distracted from the other important SAC function, namely to provide professional advice on specific items.

AER and VJ agreed to check why the CoE guide was produced annually. Means of reducing the administrative workload of SACs, so they can concentrate on their core function, need to be found.

VJ & AER

It was therefore agreed that the "Red Book" should be issued every 2 years, rather than every year. In the interim, new items or sections could be placed on the website. All SACs could nominate a few people to be responsible for drafting their relevant chapter. Videoconferencing should be encouraged to reduce travelling times.

ACTION

Post meeting note

After more careful thought, and bearing in mind TSO and UK Forum, VJ felt it important to bring out the 6th Edition in 2002 and them move to 2 yearly revisions. This has been agreed by most attendees in reply to VJ's letter of 23rd October 2001.

4.5.2. Draft remit of 'Consenting Issues' Sub-Group - JPAC Enc. 01/63

GG tabled JPAC Enc. 01/63. The main issues were; what are you consenting for and how do you get consent?

AER stated that a difficult issue is what if you can't use the tissue for its original use? Should it go to research?

"RED BOOK" 6TH EDITION 5.

SACs should start to prepare their chapters now - even if the next edition is produced in 2003 instead of 2002.

REPORT FROM UK FORUM MEETING HELD ON 5TH OCTOBER 2001 6.

6.1. SACCSD - Proposed project on donor selection criteria

On behalf of the UK Forum, AER made a formal request of VJ, as Chair of the JPAC, to ask the SAC on the Care and Selection of Donors to undertake a project to look at where the "rules" on donor selection could be clarified and if needed be modified to allow more people to donate. The remit is to look at the criteria for donor selection; consider which are the weakest in terms of evidence base and causing greatest loss of donors. AER emphasised that this has to be evidence based and risk assessed.

VJ formally agreed to this request and asked FB to undertake this work. FB will put this on the agenda for the next meeting of the SACCSD which is taking place on 16th October 2001.

FB

VJ

Following discussion on whether these rules were merely contingency, or a permanent reappraisal, AER asked BM to draft a remit for this work for the UK Forum. It was felt that a permanent reappraisal was required. BM drafted the remit which was agreed. VJ agreed to forward the remit to the UK Forum.

Kate Soldan Paper on Infectious Hazards of Transfusion 6.2.

Kate Soldan has produced an excellent paper on infectious hazards of transfusion. The paper is going to the next MSBT meeting on 22nd October 2001

6.3. **Ethics Committee ACTION**

UK Forum had agreed that an Ethics Committee to deal with ethical issues should be established. AER and Tony Napier are producing the remit and terms of reference for this group.

AER & ΑN

AER

AER will be seeking advice from Jennie Gubbins regarding the constitution of

the group.

LW asked about research activities regarding donors. AER will seek advice from Jennie Gubbins and Stephen Janisch.

AER

6.4. Chair of UK Forum

Angus Macmillan Douglas, from SNBTS, has been appointed as Chair of the UK Forum.

6.5. **SHOT**

The UK Forum has agreed, in principle, the revised budget for SHOT. More information is required on the proposed specific tasks of the National Coordinator and project development.

7. REPORT FROM COUNCIL OF EUROPE DRAFTING GROUP - JPAC Enc. 01/52

VJ gave a brief report on progress of the 8th Edition.

VJ gave FB and LW a copy of the decision of the Drafting Group, in respect of the UK submissions, as their SACs were most involved.

VJ asked them not to circulate this document, as it was an unofficial and personal record of the decisions made.

8. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

LW was awaiting approval of July's SACBC minutes before circulating to JPAC.

8.1. Joint meeting SACTTI and SACBC

This meeting will take place at the Manchester Blood Centre on Monday 26th November 2001. LW is now ready to circulate the programme.

8.2. Blood Components from outside the UK

NBS has submitted a proposal to the DoH to implement plasma importation for neonates. LW informed the JPAC that the NBS and the SNBTS are discussing the availability of other components for neonates from outside the UK.

8.3. Analysts - EOR branch of DoH

AER informed the JPAC that the NBS are to provide funding for 2 analysts who will work solely on blood issues.

8.4. **Granulocytes**

ACTION

LW informed the JPAC that a special extended meeting of the SACBC on granulocyte transfusion will be arranged for 17th May 2002..

8.5. Safety of Blood Components

LW informed the JPAC that the MSBT had asked for a paper on HIV NAT - a

paper has been provided setting out a programme of safety issues we are considering. MSBT will get regular updates on progress.

9. STANDING ADVISORY COMMITTEE ON THE CARE AND SELECTION OF DONORS

9.1. Minutes of the meeting held on 10th May 2001 - JPAC Enc. 01/53

9.2. Consultant in Transfusion Medicine - SAC

FB informed the JPAC that David Hutton has been appointed as Consultant in Transfusion Medicine - SAC, starting on 1st October 2001 and is now a member of the SACCSD.

CJS was asked to circulate a copy of the job description to SAC Chairs.

CJS

9.3. SACTTI Working Party on vCJD

FB informed the JPAC that a meeting of the Working Party on vCJD took place on 17th September by videoconference. FB was the minute secretary.

10. STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE

10.1. Membership of the SAC on Clinical Transfusion Medicine

BM stated that the membership of the SACCTM is:

Dr Frank Boulton Chair of BBTS: Hospital based transfusion practice
Dr Brian McClelland Editor: Handbook of TM (SHOT Steering Group)

Dr Mike Murphy Chair NBS Clinical Policies Group

Dr Jonathan Wallis Chair NBS Northern Regional Transfusion Committee

Dr Audrey Todd Member of SHOT Working Group
Dr Neil Smith Secretary to NBS Clinical Policies Group
Dr Clare Taylor Appropriate Use of Blood Sub-Group

Dr Dafydd Thomas Anaesthesiologist, Blood Conservation Specialist

Mrs Sandra Gray Transfusion Nurse Specialist

Mr Stephen Yates Blood Bank Manager, Blood Transfusion Service,

Southampton

Dr Kate Soldan Epidemiologist: Transfusion Microbiology and SHOT

Dr W Murphy Irish Blood Transfusion Service

The next meeting will take place on 25th October 2001 at the West End Donor Centre. To appraise the current product, discuss distribution and devise an action plan on evaluation of the book.

CJS

ACTION

BM requested a copy of the appropriate audit carried out on the use of the previous handbook.

11. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

Next meeting is on 7th December 2001.

12. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

PA could not be present at this meeting. He had therefore asked VJ to raise issues on his behalf - please see items 3.10 and 3.11.

12.1 Minutes of the meeting held on 23rd April 2001 - JPAC Enc. 01/56

13. STANDING ADVISORY COMMITTEE ON PLASMA FOR FRACTIONATION

Apologies have been received from BC. He is revising the chapter but still wants input from BPL.

VJ to ask Simon Jenkins to join the SAC.

٧J

14. STANDING ADVISORY COMMITTEE ON TISSUE BANKING

14.1. Minutes of the meeting held on 14th March 2001 - JPAC Enc. 01/57

GG informed the JPAC that 2 further meetings had taken place. A lot of time was spent discussing CJD related issues.

14.1.1. CJD Notification issues

GG informed the JPAC that they had prepared a paper on CJD notification. This has been sent to Pat Hewitt for comment

14.1.2. Bone risk assessments

GG informed the JPAC that a report on bone risk assessments had now gone to EOR.

GG stated that the Joint SACTTI and SACTB meeting last year reviewed items which still haven't been resolved.

14.2. Tissue Donor Selection Guidelines (T-DSG)

T-DSG are due at the end of the month. These are not available in a Browser version.

GG informed the JPAC that there is no difference between the NBS and SNBTS versions.

Distribution in the Blood Services is down the Quality route. Distribution outside the services ?BATB - GG to check with Ruth Warwick.

ACTION GG

The document should have official JPAC approval. GG to send to VJ for circulation to JPAC members - FB will read it and comment.

GG, VJ & FB

14.3. Malaria and Gamma Irradiation - JPAC Enc. 01/58

JPAC approved that gamma irradiation is a useful way of sterilising bone in

terms of the malaria parasite based on the evidence provided by the various working parties.

AER asked GG to inform Tim Wyatt.

GG

15. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION

15.1. Minutes of the meeting held on 3rd July 2001 - JPAC Enc. 01/59

Membership Issues - item 4.1.

Operational input to this SAC was an issue. Some members felt that an 'ops' member would add value, and BD stated that professional advice has got to include feasibility. AER said there were potential complications since implementation was a matter for individual services.

AER stated that whenever possible SACs should have people of the right calibre who could provide general advice re implementation.

JPAC endorsed the principle and an Operations person will be invited to join the SACTTI.

BD stated we need to be consulting with operational people in the NBS, SNBTS. NI and WBS.

Frank Bolton left the meeting at 14.15.

15.2. Anti HB-Core Testing

Data are rather dated. Newer more relevant data will be presented at a later date.

15.3. Problems with E-mails between NBS and SNBTS

Problems with e-mails between the NBS and SNBTS were being experienced by several SAC Chairs. VJ asked the Medical Directors of these Services to take forward to their IT departments as it was unclear where the problems lay.

AER &

16. ITEMS RAISED BY NIBSC

No items were raised.

17. ANY OTHER BUSINESS

ACTION

ALL

17.1. SAC Forward Looks

VJ asked SAC Chairs for their annual "Review" and "Forward Looks" by the end of December, so that she can prepare her report for the UK Forum in January.

18. DATE AND VENUE OF NEXT MEETING

Thursday 21st February 2002 at the West End Donor Centre, London

The meeting closed at 15.00