

Joint UKBTS/NIBSC Professional Advisory Committee

(Ex: UKBTS/NIBSC Joint Executive Liaison Committee)

**Minutes of the Twentieth Meeting held at the West End Donor Centre, London
on Thursday 14th June 2001**

Meeting commenced at 11.00 am

PRESENT

Dr Frank Boulton **(FB)** - Standing Advisory Committee on Care and Selection of Donors
 Dr Mahes de Silva **(MdS)** - Standing Advisory Committee on Immunohaematology
 Prof Ian Franklin **(IF)** - Medical Director, Scottish National Blood Transfusion Service
 Dr Henry Hambley **(HH)** - Medical Director, Welsh Blood Service
 Dr George Galea **(GG)** - Standing Advisory Committee on Tissue Banking
 Dr Virge James **(VJ)** - Chair, JPAC
 Dr Liz Love **(LL)** - Standing Advisory Committee on Transfusion Transmitted Infection
 Dr Brian McClelland **(BM)** - Standing Advisory Committee on Clinical Transfusion Medicine
 Dr Morris McClelland **(MM)** - Medical Director, Northern Ireland Blood Transfusion Service
 Dr Peter Phillips **(PP)** - National Institute of Biological Standards and Control
 Dr Angela Robinson **(AR)** - 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 George Galea as Chair of the Standing Advisory Committee on Tissue Banking.

1. APOLOGIES

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
 Dr Morag Ferguson **(MF)** - National Institute of Biological Standards and Control
 Dr Mike Kavanagh **(MK)** - Medicines Control Agency
 Dr Geoffrey Schild **(GS)** - National Institute of Biological Standards and Control

2. MINUTES OF THE NINETEENTH MEETING HELD ON 14TH FEBRUARY 2001

ACTION

The minutes were approved as an accurate and true record with 1 amendment.

2.1. Alteration to action on item 7.2. Briefing paper on FFP and plasma in other components

Action to read: LL SACTTI

3. MATTERS ARISING

ACTION

- 3.1. **“Red Book” Archive - item 3.2.**
Progressing.
- 3.2. **Council of Europe Guidelines “Guide to the preparation, use and quality assurance of blood components” 8th Edition - Consultative phase - item 3.3.**
Virge James reaffirmed that comments were required by 6 July 2001 **All**
- 3.3. **Current difficulties and possible solutions - item 6.2.2.**
Virge James is attending one meeting of each of the SACs. **VJ**
- 3.4. **Indemnity - item 6.3.**
Virge James reminded the SAC Chairs that she requires an up-to-date list of their membership so that new members can receive indemnity letters where relevant **All**
It was agreed that Chairs may circulate JELC Enc. 01/32, Letter from Gail Williams, to their membership. **All**
Clarification on indemnity is still required. Virge James agreed to take this matter to Gail Williams. **VJ**
- 3.5. **Handbook of Transfusion Medicine - item 9.1.**
Granulocyte transfusion - Policy is being drafted by the NBS Clinical Policies Group. A joint meeting of the SACBC, SACCSD and the JPAC will be organised later in the year, with a view to a UK wide policy.
Ian Franklin informed the JPAC that he and Mike Murphy want to encourage a trial, and that a German trial on efficacy of granulocytes would be looked at once it has been translated.
Angela Robinson informed the JPAC that some people still use buffy coats and any policy should also consider this practice.
- 3.6. **European ad hoc Working Group regarding the CTS for list B devices - item 10.2.**
Peter Phillips informed the JPAC that this was effective from June 2000 and not June 2001.
Angela Robinson had written to Alan Slopecki, NBS Head of Operational Quality, regarding the CE marking of reagents.
Alan Slopecki confirmed the following:
“Is the NBA one legal entity for CE marking?”
Yes it is and even though we operate on multiple sites advice from the MDA has indicated that this will not in itself result in a need for formal CE marking. **ACTION**

Do reagents supplied to hospitals require CE marking?

Yes If we supply reagents to any other legal entity then we will have to have CE marking.

Will current practices be compliant when the directive comes into force in June this year?

Yes there is a transition period as there was for medical devices allowing CE and non CE marked materials to be available on the market at the same time. This runs out end of 2003 after which if we are not CE marked we will not be able to supply outside our legal entity.

The reason (and the only reason) that we do not need to CE mark reagents for our own purposes is that because we are part of the NHS, and hence Government, it is assumed that we will fully comply with any requirements without the need to be externally assessed. Therefore if we make reagents for internal use we must ensure that the systems we use are as good as the systems that a manufacturer registered with a notified body would employ.”

3.7. Labelling for patient notes - item 11.4.

Lorna Williamson will take this issue to the next BCSH meeting on 3 July 2001. The JPAC felt that although it was not our responsibility to write guidelines for hospital labels we could offer advice.

LW**3.8. Council of Europe draft “Guide on Safety and Quality Assurance for Organs, Tissues and Cells” - item 13.2.**

JPAC comments have been collated by Ruth Warwick and sent to the Department of Health.

Virge James requested a copy of the formal response to the CoE document for the JPAC records and archiving.

GG**3.9. MAD-T - item 13.5.**

Concessionary Letter UK National Blood Service No. 1 - 2001, regarding a change to MAD-T was issued on 12 March 2001.

3.10. Reinstatement of donors who have false positive screening tests (JELC Enc. 01/31) - item 14.5.

Angela Robinson to formally write to Roger Eglin, Chris Hodson and Peter Garwood regarding the reduction of the waiting period from 6 months to 12 weeks.

AR**3.11. Proposed Parasitic Infection Committee - item 14.6.**

A Working Party on Parasitology and Blood Safety, Chaired by Dr Peter Chiodini, has been set up and has met (see items 8.4. and 8.5.).

4. RED BOOK ADMINISTRATION**ACTION****4.1 New Chairs**

Virge James officially welcomed George Galea as the new Chair of the SAC on Tissue Banking

4.2. **TSO website**

Work on production of a website for the "Red Book" is progressing. Virge James will be meeting with Paul Ashford, Serge Six and Richard Middleton from TSO to discuss the website. Virge James informed the JPAC that TSO have quoted £19,000 to set the website up. Alternatives are also under discussion.

VJ

4.3. **Travelling expenses for non NBS SAC members**

The JPAC agreed that SAC Chairs should deal with enquires regarding travelling expenses from non NBS members as they arise and that if expenses were really necessary they could be reimbursed from the "Red Book" budget. Generally, however, it was felt that contributing to a Standing Advisory Committee (SAC) is to be regarded as an NHS commitment.

All

4.4. **Quality - Is this a "Red Book" or UK Forum function?**

After discussion the JPAC agreed that there should not be a separate SAC on Quality, but that revision of the relevant chapter should be a collaborative effort between the Quality Managers in the 4 Services.

4.5. **Adverse events of donation - Is this a "Red Book" or UK Forum function?**

The SAC on Care and Selection of Donors will produce proposals for defining the adverse events on which information should be collected. The 4 Services will collect the information and make it available to each other and the JPAC.

FB

5. **"RED BOOK" 5TH EDITION**

Virge James appraised the JPAC on the progress of the 5th Edition.

- The proofs have arrived at Virge James' office for comment
- Virge James is meeting with Helen Bodenham from TSO on 15th June to go through the proofs
- For clarity it was agreed that MAD and MAD-T would be referred to as Supplements 1 and 2 in the 5th Edition

6. **REPORT FROM UK FORUM MEETING HELD ON 6TH APRIL 2001**

6.1. **Letter from Gail Williams, Director of the Welsh Blood Service - JELC
Enc. 01/32**

It was agreed by the JPAC that this committee would now be known as the "Joint UKBTS/NIBSC Professional Advisory Committee" (JPAC).

All

6.2 **Review/Forward look**

ACTION

Virge James will produce a review/forward look for the UK Forum annually with the next one due in January 2002.

7. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

- 7.1 **Minutes of the meeting held on 17 October 2000 - JELC Enc. 01/33**
Minutes of the meeting held on 5 February 2001 - JELC Enc. 01/34

7.2. **MSBT discussion on plasma**

Lorna Williamson briefed the meeting on recent discussions with MSBT at a meeting in April.

MSBT secretariat will formulate a recommendation to Ministers.

The issue of Appropriate Usage should be taken forward by the 4 Services as appropriate (including Hospital Transfusion Committees).

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

- 8.1. **Minutes of the meeting held on 19 February 2001 - JELC Enc. 01/35**

- 8.2. **Draft document by Frank Boulton - based on letter sent to gay rights students activist group - JELC Enc. 01/36**
Safety of Blood Leaflet - draft version 3 - JELC Enc. 01/37
Safety of Blood Leaflet - supporting document February 2001 - JELC Enc. 01/38

The Safety of Blood Leaflet has been sent to the Expert Advisory Group on AIDS, the membership of which has recently been extended to include a representative from the Terrance Higgins Trust.

The statement that "men who have had sex with men must never give blood" had raised concerns. Nevertheless, due to epidemiological information in the UK the SAC on Care and Selection of Donors recommends a life time ban.

Discussion on the Safety of Blood Leaflet has been deferred until the September meeting of the MSBT. The new leaflet is not therefore imminent. A paper is being prepared for this meeting by Kate Soldan, which will provide as much relevant epidemiological data as is currently available and will attempt to assess the impact of relaxing our current risk criteria.

Lorna Williamson commented that we should emphasise our first principle is safety.

8.3. **Haemochromatosis**

It was emphasised that the guidelines, as written, allow the 4 Services to follow independent appropriate courses.

8.4. **Proposals for revised T.cruzi selection criteria - JELC Enc. 01/44**

ACTION

Liz Love and Frank Boulton went through these proposals for the JPAC. Although formally they should have been considered by SACTTI before coming to the JPAC, time constraints are such that the JPAC were asked to approve

subject to SACTTI approval.

**8.5. Working Party on Blood Parasites (Malaria)
Draft Minutes of the meeting held on 12 April 2001 - JELC Enc. 01/47**

Liz Love went through these minutes for the JPAC. Although formally they should have been considered by SACTTI before coming to the JPAC, time constraints are such that the JPAC approved subject to SACTTI approval.

8.6. Changes in MAD 008

These will be known as Donor Selection Guidelines (DSG) and are due out in July 2001. This change in name may help universalisation throughout the 4 Services.

The Services expect a 3 month implementation time. As previously agreed the dates in the DSG will be the date when the changes were approved by the JPAC i.e. 14.06.01. The Services are now responsible for documenting their implementation dates.

The changes are:

- T.cruzi, malaria - if approved by SACTTI
- CJD - 2 family members affected before resulting in donor deferral. This will be in line with CoE guidance. Rules apply to all forms of CJD not just vCJD.

Ian Franklin raised the issue of using the word "mandatory". It was agreed that "not discretionary" would be better than "mandatory". Frank Boulton will take forward.

Post Meeting Note:

As it would take up a lot of text space to replace "mandatory" with "not discretionary" it was agreed to use the word "obligatory" instead.

Lorna Williamson left the meeting at 1.20 pm

Frank Boulton informed the JPAC that David Hutton had resigned from the Working Group on MAD guidelines. Frank Boulton would like to offer his sincere thanks to David for all his hard work and hope that he can work for us in the future.

9. STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE

9.1. Handbook of Transfusion Medicine Report - JELC Enc. 01/49

Tabled by Brian McClelland.

Brian McClelland asked for any comments on the key tasks, liaisons and the suggested membership of the SAC from the JPAC within the next few days.

**ACTION
All**

Ian Franklin suggested contacting HITs (Haematologists in Training) for a representative. The JPAC also thought a BBTS representative would be beneficial.

9.2. **Distribution of the Handbook of Transfusion Medicine**

Brian McClelland informed the JPAC that 5,000 copies of the Handbook were available "free of charge" (£10,000 having been paid to TSO).

The following distribution of the Handbook was agreed by the JPAC. Brian McClelland would forward this information to TSO.

BM

<u>Service</u>	<u>No. of free copies</u>	<u>Contract name for distribution</u>
NIBTS	250 (5%)	Dr Morris McClelland
SNBTS	500 (10%)	Caroline Lang (SNBTS Headquarters)
WBS	250 (5%)	Dick Jones (WBS Headquarters)
NBS	4000 (80%)	Stuart Penny (NBS Colindale)

The JPAC agreed that Brian McClelland could look into further marketing of the Handbook.

BM

9.3. **Proposal for a website**

The JPAC agreed that the Handbook has to be an open document. Virge James agreed to forward an email she had received from Serge Six containing website information to Brian McClelland.

CJS

10. **STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY**

10.1. **Chapter on standards for reagents using automated equipment**

Mahes de Silva informed the JPAC that a working group was looking into producing a chapter on standards for reagents used in automated equipment.

10.2. **Resignation of Chair of SAC on Immunohaematology**

Mahes de Silva formally resigned as Chair of the SAC on Immunohaematology. Virge James thanked Mahes de Silva, on behalf of the JPAC, for her work as Chair of this committee.

Virge James will be writing to members of the JPAC asking for nominations for a new Chair.

VJ

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

Paul Ashford could not be present at this meeting. He had therefore asked Virge James to raise several issues on his behalf.

11.1 **Minutes of the meeting held on 15 January 2001 - JELC Enc. 01/43**

ACTION

11.2. **ISBT Code 128**

A briefing paper on ISBT Code 128 has been sent to the UK Forum and will be discussed at their next meeting.

11.3. **EDI messaging**

Paul Ashford wished to advise the JPAC that they are continuing to monitor the development of EDI messaging standards in Europe and the USA and to indicate that we continue to have concerns over the lack of communication between the two groups.

He asked for JPAC agreement that the SACIT could take out organisational membership of the UK HL7 affiliated group which contributes to the development of the standards in the USA. The organisational membership fee is £500 + VAT per annum.

The JPAC agreed to cover the cost of organisational membership of this group, but asked that SACIT report back to the JPAC after 12 months to justify a further spend. PA

11.4. **Membership of SAC on Information Technology**

Ian Franklin expressed concerns over the lack of medical input on the SACIT. Dr Phil Yates has been invited to join the group. It was suggested that consideration be given to inviting Dr Serge Six onto this committee. PA

Peter Phillips left the meeting at 2.15 pm

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

Bruce Cuthbertson has reviewed the chapter for the 5th Edition and is currently getting a small team together for this SAC and the next revision.

13. **STANDING ADVISORY COMMITTEE ON TISSUE BANKING**

13.1. **Minutes of the meeting held on 7/8 December 2000 - JELC Enc. 01/39**

13.2. **Parental exposure to animal products**

A paper has been prepared on parental exposure to animal products. This has gone to the SACTTI.

13.3. **CJD notification and Tissue Donors**

George Galea informed the JPAC that the SACTB are currently drafting a paper on CJD notification and Tissue Donors.

13.4. **Risk Assessments of bone donors by sub-group - draft No. 5** **ACTION**

Needs to go to EOR via Liz Love. Liz Love to check this is the correct route. LL

13.5. **MAD-T**

MAD-T will be renamed as Tissue Donor Selection Guidelines.

MAD-T is under major revision and will include cord blood. The updated version could be ready in October 2001.

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

- 14.1. **Minutes of the meeting held on 22 January 2001 - JELC Enc. 01/40**
Minutes of the meeting held on 13 March 2001 - JELC Enc. 01/41

- 14.2. **Minutes of the meeting held on 1 May 2001 - JELC Enc. 01/42**

Liz Love went through these minutes for the JPAC.

- **Item 4.2. HCV PCR and reduction of deferral period**

SACTTI recommends reduction from 12 to 6 months only if anti-HB core testing is in place. A paper on anti-HB core testing is in preparation by the SACTTI.

- **Item 5. vCJD Working Group**

This Working Group was approved by the JPAC.

JPAC felt that a Tissues representative would be beneficial to this group. Liz Love will discuss this with Marc Turner who has agreed to chair the Group and George Galea will suggest a suitable person.

LL
GG

Liz Love had forwarded a draft of the Group's terms of reference and proposed membership to Virge James, but was awaiting confirmation of membership before wider circulation.

It was also agreed that it would be appropriate to invite Bruce Cuthbertson to join the Group to provide expertise from a plasma fractionator's position.

LL

- **Item 6. Bacterial Contamination**

Liz Love went through a draft document produced by John Barbara. This document would be circulated to the JPAC when approved by the SACTTI.

- **Item 8. Extension of NAT: position paper**

A request to provide a position paper on HIV NAT for the MSBT had evolved into much wider issues of blood safety which the NBS had been asked to consider. A draft paper had been produced (and made available to JPAC members) as a first response to this process. SACTTI papers on individual issues (e.g. bacterial testing, anti-HB core testing) will form appendices to the main document. The JPAC needs to recognise that the paper needs more work, particularly in the provision of background evidence and risk assessment.

ACTION

15 **ITEMS RAISED BY NIBSC**

No items were raised.

16. **ANY OTHER BUSINESS**

16.1. **Resignation of Dr Henry Hambley**

Henry Hambley, Medical Director WBS, informed the JPAC that this would be his last meeting as the representative from Wales.

Virge James thanked Henry Hambley on behalf of the JPAC for his contribution to the committee.

16.2. **Japanese translation of the “Red Book”**

Virge James informed the JPAC that she had received a request from Dr Ryushi Shimoyama, Hokkaido Red Cross Blood Centre, asking if they could translate the “Red Book” into Japanese. The JPAC agreed to this request in principle, but further advice would be sort from TSO before agreement is given.

VJ

16.3. **Ethics Committee**

Gail Williams is pursuing. Ian Franklin to email Virge James

IF

16.4. **Department of Health Clinical Incident Advisory Panel CJD**

Angela Robinson informed the JPAC that the promised interim guidance has still not been agreed for people exposed to plasma derivatives and is not yet available.

17 **DATE AND VENUE OF NEXT MEETING**

Thursday 11th October 2001 at the West End Donor Centre, London

The meeting closed at 15.10

MEETING DATES FOR 2002 - VENUES TO BE CONFIRMED

- Thursday 21st February
- Thursday 13th June
- Thursday 10th October