

UKBTS/NIBSC Joint Executive Liaison Committee

Minutes of the Nineteenth Meeting of the Joint Executive Committee
held at Birmingham New Street Conference Suite, Birmingham
on Wednesday 14th February 2001

Meeting commenced at 11.00

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 Mahes de Silva (MdS) - Standing Advisory Committee on Immunohaematology
Dr Morag Ferguson (MF) - National Institute of Biological Standards and Control
Prof Ian Franklin (IF) - Medical Director, Scottish National Blood Transfusion Service
Dr Henry Hambley (HH) - Medical Director, Welsh Blood Service
Dr Virge James (VJ) - Chair, JELC
Dr Liz Love (LL) - Standing Advisory Committee on Transfusion Transmitted Infection
Dr Mike Kavanagh (MK) - Medicines Control Agency
Dr Angela Robinson (AR) - Medical Director, National Blood Service
Dr Ruth Warwick (RW) - Standing Advisory Committee on Tissue Banking
Dr Lorna Williamson (LW) - Standing Advisory Committee on Blood Components

IN ATTENDANCE

Miss Caroline J Smith (CJS) - Minute Secretary

1. APOLOGIES

Action

Apologies were received from:

Dr Brian McClelland - Standing Advisory Committee on Clinical Transfusion
Medicine
Dr Morris McClelland - Medical Director, Northern Ireland Blood Transfusion
Service
Dr Geoffrey Schild - National Institute of Biological Standards and Control
Dr Peter Phillips - National Institute of Biological Standards and Control

2. MINUTES OF THE EIGHTEENTH MEETING HELD ON 25TH OCTOBER 2000

The minutes were approved as an accurate and true record.

3. MATTERS ARISING

3.1. Ethical Committee

Gail Williams, Chief Executive of the Welsh Blood Service, is preparing a
business case on behalf of the UK BTS Forum.

3.2. “Red Book” Archive

Action

The Committee agreed that temporary assistance would be needed to set-up a “Red Book” archive. This archive would also contain relevant European documents. Virge James to organise reasonably promptly.

VJ

3.3. **Council of Europe Guidelines “Guide to the preparation, use and quality assurance of blood components” 8th Edition - Consultative phase**

Once these have been approved by SP-H-M in April Angela Robinson will send to Virge James to circulate to JELC members for comment.

ARVJ

4. **NEW CHAIRS**

4.1 Virge James welcomed Paul Ashford as Chair of the SAC on Information Technology.

4.2 Virge James informed the committee that Dr Bruce Cuthbertson had accepted the appointment of Chair of the SAC on Plasma for Fractionation.

5. **“RED BOOK” 5TH EDITION**

Virge James had met with Richard Middleton, from The Stationery Office (TSO), with regard to production of the 5th Edition of the “Red Book.

Several editorial format modifications had been discussed which included:

- Number chapters consecutively throughout the book
- Reduce paragraph numbering
- Number all tables and illustrations within the chapter
- Tabulate material for easy reference and reduce repetition
- Put all contacts, references and appendices at the back of the book
- Avoid repeating the words “guidelines” and “specifications”
- Include an index
- Mark changes in content

Several members of the Committee requested that the Electronic Version of the “Red Book” be searchable. Virge James to take to TSO.

VJ

Virge James also appraised the Committee of a proposed website which would link from the TSO website and would contain the “Red Book”. It will also contain copies of MAD, MAD-T and other publications if required. Virge James was awaiting more information from Richard Middleton.

Angela Robinson requested that when Virge James had the relevant information she could write an article for Blood Matters and send information to Ian Franklin.

VJ

6. REPORT FROM UK FORUM MEETING HELD ON 26TH JANUARY 2001

Action

6.1. "Red Book" Organisation - Review 2000

Virge James informed the Committee that the "Red Book" Organisation Review 2000 had been accepted by the UK Forum. There is still some uncertainty about SACIT. It had been decided to leave it within the "Red Book" for the time being.

6.2 "Red Book" Organisation - Annual Report 2000

The UK Forum accepted the "Red Book" Organisation - Annual Report 2000 and felt that on the whole the organisation was doing well.

It was agreed that SHOD (Serious Hazards of Donation) should, in the first instance, collect data on serious adverse events only. Both this and the apheresis incident report should come through the JELC.

Ian Franklin informed the Committee that these reports need to go through the 4 Services as part of Clinical Governance.

VJ

Liz Love also stated that information on autologous adverse events should be collected.

FB

Ruth Warwick informed the Committee that adverse stem cell and bone marrow harvesting events are under consideration for collection by BSBMT.

6.2.1 Evidence Based Guidelines

Henry Hambley informed the Committee that a Job Description had been tabled at the UK Forum and that this is being progressed by Gail Williams.

6.2.2 Current difficulties and possible solutions

Virge James will be meeting with Gail Williams on 2nd March to discuss communication between the "Red Book" and other organisations. She also hopes that the UK Forum will pursue the development of 1 overarching UK blood safety group with the various government offices.

Liz Love asked that the Committee receive feedback from this meeting.

VJ

It was agreed that both the Review and the Annual Report, as submitted to the UK Forum, could be circulated to SAC members. Electronic copies would be sent to the SAC Chairs for onward distribution.

CJS

6.3. Indemnity

Frank Boulton raised concerns regarding indemnity.

Virge James stated that indemnity was offered to NBS, and hospital and university SAC members in England, on the same basis as LREC.

The UK Forum is clarifying the position in the other Services.

Members need confirmation of indemnity in writing.

Action

Virge James asked all SAC chairs to send an up-to-date list of their SAC members to Caroline Smith. Virge James will write to all new SAC members.

All
VJ

7. STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS

7.1 Safer Plasma in Components (SPIC). Paper for MSBT on options for future provision of clinical fresh frozen plasma - JELC Enc. 01\3

This paper was considered at the MSBT meeting in January.

7.2. Briefing paper on FFP and plasma in other components - JELC Enc. 01 \30

Lorna Williamson briefed the meeting on recent discussions with MSBT.

There were general concerns that the clinical usage should be revisited. There was scepticism about the figures produced by EOR.

Concerns were expressed about the remaining activity in FFP following numerous steps to achieve further safety and the possible need for greater donor exposure. Concern was also expressed about availability.

A lively and prolonged discussion ensued, and finally having heard the arguments, members of the JELC were asked to give their preferred solution for safer FFP. Lorna Williamson stated that it would be very helpful if a coherent view could be taken from JELC for a future MSBT meeting.

The majority view was that commercial virally inactivated product offered the more controlled material.

Several action points arose . Angela Robinson stated that in general virologists are opposed in principle to the use of pooled products, but that this position needs to be reviewed and more evidence based.

TRALI: We need to find out if there are problems with TRALI. The Blood Services should monitor the clinical use of FFP and adverse events associated with FFP transfusion. SACTTI had in the past expressed concerns about the SD product, but it is now time to review the situation.

LL
SHOT

A recommendation will be made in April at a special meeting of the MSBT, meanwhile the UK Blood (Transfusion) Services have been asked to establish whether or not a secure, sustained supply of virally inactivated clinical FFP can be obtained from BSE and vCJD free countries.

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

8.1. Minutes of the held on 4 October 2000 - JELC Enc. 01\4

8.2. Haemochromatosis

- **Blood Donation and Haemochromatosis - JELC Enc. 01\6**
- **EASL International Consensus Conference on Haemochromatosis**

Action

- JELC Enc. 0117

- **Guidance for Industry. Variances for Blood Collection from Individuals with Hereditary Hemochromatosis - JELC Enc. 0118**
- **Blood Donation from People with Genetic Haemochromatosis - JELC Enc. 0119**

The SACCSO recommends acceptance of people with haemochromatosis as blood donors as long as they meet the MAD/A-Z criteria. Symptomatic people would not be accepted.

Virge James reported from SP-R-GS. Prof. Heier had presented a paper on the acceptability of haemochromatosis patients as blood donors. The conclusion was that the blood is safe for transfusion, but all health or financial gain must be removed from the donation process, so it remains voluntary, non-remunerated.

This will be in the CoE Consultation document - 8th Edition.

The JELC accepts the principles put forward.

Frank Boulton to write to the Medical Directors. The decision rests with the Services.

FB

8.3. **Safety of Blood Leaflet - JELC Enc. 0115**

This has not yet been presented to MSBT, but hopefully will make the next meeting.

Frank Boulton went through the changes for the JELC. The JELC endorsed these changes, but would like to see the suggested wording (a) taking haemophiliacs out and (b) changes to the Africa clause.

9. **STANDING ADVISORY COMMITTEE ON CLINICAL TRANSFUSION MEDICINE**

9.1. **Handbook of Transfusion Medicine**

Virge James discussed the Handbook of Transfusion Medicine in the absence of Dr Brian McClelland.

Brian McClelland had raised the issue of indemnity.

Virge James noted the disclaimer clause in "Guidelines for Blood Banking", Transfusion 2000, 10, 307-314, produced by the BCSH Transfusion Task Force. Virge James to ask Paul Kelsey (Chair of BCSH Blood Transfusion Task Force) and Robert Marcus (BCSH Guideline Director) whether this had been legally approved, in which case it could be used for the handbook.

VJ

Concern was raised about the chapter on directed donation which may need an affirmation of the principle that in the UK directed donation is discouraged.

Virge James to forward draft Handbook to JELC members. Virge James to contact Brian McClelland.

**Action
VJ**

Ian Franklin mentioned that a UK wide policy for granulocyte transfusion would

be beneficial.

Virge James to write to the Apheresis sub-group.

VJ

10. STANDING ADVISORY COMMITTEE ON IMMUNOHAEMATOLOGY

10.1 **Minutes of the SAC for Immunohaematology (Red Cell Immunohaematology\Automation Sub Committee) meetings on:**

13 October 2000 - JELC Enc. 01\10

08 December 2000 - JELC Enc. 01\11

19 January 2001 - JELC Enc. 01\12

10.2. **European ad hoc Working Group regarding the CTS for list B devices**

Mahes de Silva appraised the JELC on the EU CTS Medical Devices Directive. Effective from June 2001, (3 year leeway) this will impact on the reagents we use.

Angela Robinson to write to MDA to (1) confirm whether the Services are single legal entities and (2) do we need CE mark for our reagents used within hospitals in the UK.

AR

10.3. SACI contributes to SACBC section on mandatory testing on blood groups. There are no guidelines for HLA or HPA typing platelets. A draft had been sent to SACBC by Paul Metcalfe. Lorna Williamson to provide comments back.

LW

10.4. **Patient Testing - on tests for hospitals**

Future editions will include specialist areas not covered by BCSH guidelines and cross references. i.e. quantitation.

MdeS

11. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

11.1 **Minutes of the meeting held on 3 July 2000 - JELC Enc. 01\13**

Minutes of the meeting held on 2 October 2000 - JELC Enc. 01\14

11.2. **Electronic Despatch Note**

Paul Ashford informed the Committee that the electronic despatch note is now being made available to some hospitals. Information placed into electronic despatch notes needs to be rigorously controlled. There is a need to make sure that appropriate links are maintained between the groups involved in maintaining guidelines for handling electronic information (SACIT and BCSH).

The existing version of the standard allows for red cell phenotyping information to be included. Platelet typing information will be included in the next version, together with additional messages to support blood product (derivatives) and reagent despatch information.

Action

11.3. **ISBT 128**

SACBC & SACIT working on ISBT 128 - mapping - this should be available in the next few months.

Specification for blood bag base labels is progressing.

European manufacturers are looking at using symbols rather than text on bags. A long lead-in phase needed before we decide if we can use this system.

11.4. **Labelling for patient notes**

Producing a label which would be taken directly from the unit and put in the patient notes was discussed.

It was noted that some hospitals are beginning to produce their own labels. The BCSH need to produce guidelines on a safe way to do this.

LW

11.5. **Bedside ISBT 128 labels**

Denmark and other countries produce additional bedside ISBT 128 labels for use at the bedside.

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

The new chair, Dr Bruce Cuthbertson, will attend future meetings and review the current chapter.

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

13.1. **Minutes of the meeting held on 23 March 2000 - JELC Enc. 01\15**

Minutes of the meeting held on 22 June 2000 - JELC Enc. 01\16

Minutes of the meeting held on 7 September 2000 - JELC Enc. 01\17

13.2. **Council of Europe draft "Guide on Safety and Quality Assurance for Organs, Tissues and Cells"**

Ruth Warwick explained that each Country is required to submit a single document containing comments and/or suggested changes. She has prepared a template for comments. Virge James will circulate hard copies of the guide to JELC members and e-mail Ruth Warwick's electronic template for comments to ensure uniformity. Ruth Warwick will collate JELC comments. The deadline is 18th May - internal deadline is 16th April.

VJ\
CJS
RW

13.3. **US Department of Health & Human Services Office of the Inspector General: "Oversight of Tissue Banking - January 2001" - JELC Enc. 01\18**

Ruth Warwick drew to the attention of the JELC members to bullet point 2 - inspection of Tissue Banks. If undertaken here this would be a vast task.

Action

Correction to bullet point 9 should read "The AATB has accredited 58 tissue banks....."

A full version of this document is available from Ruth Warwick.

13.4. **vCJD and Donors of Tissues Who Died by Suicide - JELC Enc. 01\19**

In a snap shot view 5% of cadaver tissues were suicides.

Ruth Warwick had noted a conversation with Bob Will which in essence concludes that accepting tissues from suicides would not result in an increased risk of transmission of vCJD.

13.5. **MAD-T**

MAD-T is under revision to include cord blood and a rationale will be brought to JELC in due course.

In the light of a future test for vCJD becoming available results could be correlated with findings on brain, appendix and tonsil. Perhaps cadaver donors of tissues should be the first donors to have any test applied. Ruth Warwick is consulting.

Ruth Warwick also pointed out that developments in the field of pancreatic islet cells has led to a number of transplant centres approaching the NBS.

Malaria: Current MAD states defer if resident in malaria area etc. for 3 months in first 5 years of life. Recent MSBT guidance on organs and tissue cells states residence 3 months at **any time of life.**

Ruth Warwick would like a concessionary letter for MAD-T realising that this would then not be consistent with MAD/A-Z. Following discussion it was agreed that a concessionary letter will be issued as soon as possible.

VJ

13.6. **Resignation of Chair of SACTB**

Ruth Warwick formally resigned as chair of the SACTB. Virge James thanked Ruth Warwick, on behalf of the JELC, for her work as chair of SACTB.

Virge James will be writing to the members of the JELC asking for nominations for a new chair.

VJ

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

14.1. **Minutes of the meeting held on 19 September 2000 - JELC Enc. 01\20**

14.2. **SACTTI: Screening donations for HTLV Report for MSBT September 2000 - Revised 09\01\01 - JELC Enc. 01\21**

Testing had been recommended by SACTTI (this position had not changed since the first paper to MSBT in 1996), agreed by the JELC and endorsed by NBA Board. The general (as yet unminuted) view of the MSBT was that a risk assessment would not provide much additional information and that the MSBT should recommend that testing should be implemented. The NBS had been requested to undertake a feasibility and costing study and to simultaneously commission a risk assessment, if possible.

Action

When testing is implemented, policy guidelines will be needed for any

“Lookback” cases that arise as a result. Confirmation of MSBT/DoH recommendation is awaited, which will need to take into account the NBS feasibility and costing exercise.

Morag Ferguson informed the Committee that the NIBSC have got a standard for HTLV-I testing.

Ian Franklin informed the Committee that the Scottish Executive have told SNBTS to go ahead. (A pilot study showed 1 in 85,000 positive donors in Scotland)

14.3. SACTTI - Sub-Committee on Technical Aspects

The SACTTI had recommended disbanding this sub-committee and dealing with subjects as they arise in short term working groups - this was approved.

14.4. Proposal for the establishment of a vCJD Working Group

SACTTI would like support to convene a working group under the chairmanship of Marc Turner to deal with keeping up-to-date on world issues on vCJD. It would be a knowledge based group. Liz Love asked JELC members to let her have any suggestions for membership of this working group. This working group was approved.

Liz Love asked that JELC members e-mail her by next Friday (23 February 2001) with suggested membership and issues for discussion.

Angela Robinson stated that the Services have to react quickly. Medical Directors could call together groups for rapid response as issues arise.

14.5. Reinstatement of donors who have false positive screening tests - JELC Enc. 01\31

SACTTI are happy to support a recommendation for a reduction in waiting period from 6 months to 12 weeks. The JELC supported this view. Virge James and Liz Love to write to the Medical Directors.

VJ\LL

14.6. Proposed ‘Parasitic infection Committee’ (Chair: Peter Chiodini)

The formation of this working group of SACTTI was approved. Liz Love will oversee the topics discussed.

LL

15. JOINT MEETING OF THE SACS ON BLOOD COMPONENTS AND TRANSFUSION TRANSMITTED INFECTION

15.1. Minutes and attachments from the meeting held on 22 November 2000 - JELC Enc. 01\23

Amended minutes will be issued.

LL

Presentation - JELC Enc. 01\24

Philips Report: 27 October 2000 - JELC Enc. 01\25

WHO Consultation on Blood Safety Policy: An International Perspective - JELC Enc. 01\26

Options for Minimising the Potential for BSE/vCJD Transmission of Human Allogeneic Blood and Tissue Transfer - JELC Enc. 01\27

Recipients According to TSE Risk of Allogeneic Transfusion - JELC Enc. 01\28

Risk Reduction - Bone Allografts - JELC Enc. 01\29

16. ITEMS RAISED BY NIBSC

No items were raised.

17. ANY OTHER BUSINESS

No further items were raised.

18. DATE AND VENUE OF NEXT MEETING

Thursday 14th June 2001 at the West End Donor Centre, London

The meeting closed at 15.35