

Joint UKBTS Professional Advisory Committee

Minutes of the 65th meeting held in the Boardroom at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB on Thursday 10 November 2016

Meeting commenced at: 11:05

Present

Dr Neil Almond	(NA)	- National Institute for Biological Standards and Control - <i>Deputising for Dr Christian Schneider</i>
Dr Stuart Blackmore	(SB)	- Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	(RC)	- Standing Advisory Committee on Blood Components
Dr Akila Chandrasekar	(AC)	- Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	(SF)	- Medical Director, Welsh Blood Service
Dr Alan Kitchen	(AK)	- Standing Advisory Committee on Transfusion Transmitted Infections
Mrs Linda Lodge	(LL)	- Standing Advisory Committee on Information Technology
Mrs Angela Macauley	(AM)	- Quality Manager, Northern Ireland Blood Transfusion Service representing the Quality Managers of the 4 UK Blood Services - <i>deputising for Mr Tony Docherty</i>
Dr Sheila MacLennan	(SM)	- Professional Director of JPAC (Chair)
Dr Gary Mallinson	(GMal)	- Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Kieran Morris	(KM)	- Medical Director, Northern Ireland Blood Transfusion Service
Miss Caroline Smith	(CJS)	- JPAC Manager (Minute taker)
Dr Shirley Stagg	(SS)	- Human Tissue Authority (HTA)

SM welcomed Dr Stuart Blackmore to his first meeting since taking over as Chair of the SAC on Care and Selection of Donors, Dr Neil Almond who was deputising for Dr Christian Schneider and Mrs Angela Macauley who is deputising for Mr Tony Docherty.

Prof Ian Hann has been appointed as the interim National Medical Director for the Irish Blood Transfusion Service, but unfortunately he could not attend today's meeting.

SM also informed the committee that David Carter, the MHRA representative on JPAC, had passed away in August. David had been a valued member of JPAC since July 2013 and would be greatly missed.

1.

Apologies

Mr Tony Docherty	(TD)	- Quality Manager, Scottish National Blood Transfusion Service
Prof John Forsythe	(JF)	- Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
Prof Ian Hann	(IH)	- Interim National Medical Director, Irish Blood Transfusion Service
Dr Gail Mifflin	(GM)	- Medical Director, NHS Blood and Transplant
Dr Megan Rowley	(MR)	- Standing Advisory Committee on Clinical

ACTION

ACTION

		Transfusion Medicine
Dr Christian Schneider	(CS)	- Director, National Institute for Biological Standards and Control
Prof Marc Turner	(MT)	- Medical Director, Scottish National Blood Transfusion Service
Prof Maria Zambon	(MZ)	- Director, Centre for Infections, Public Health England (PHE)
Dr Nay Win	(NW)	- Standing Advisory Committee on Immunohaematology

2. **Minutes of the last meeting held on 23 June 2016 – JPAC 16-74**

The minutes were approved as a true record of the meeting, with one amendment to item 14.2. - the action is on RC not GM.

3. **Matters arising not on the agenda (Review of actions list) JPAC 16-75**

3.1 **Perfusion of organs – item 14.2**

RC has discussed this issue with Prof John Forsythe and a member of John's team will give a presentation at the next SACBC in January 2017. RC will report back to JPAC at the next meeting.

RC

3.3 **High titre testing of pool platelets in PAS – item 14.3**

Work in progress – NW is awaiting some information from Australia.

4. **Standing Advisory Committee on Blood Components**

4.1 **Review of EuroBlood Pack Data – JPAC 16-76**

This paper was circulated for information and noted by JPAC.

4.2 **Changes to Chapter 8 relating to platelet and red cell evaluations – JPAC 16-77**

Recently guidance relating to interruption of platelet agitation and removal of red cells from a controlled temperature environment has been reviewed by SACBC (JPAC 15-35 and JPAC 15-54). One of the recommendations from the review was that when UKBTS are validating significant changes to red cell or platelet component production/storage, consideration should be given with respect to including such deviations from controlled storage as part of that process.

JPAC approved these changes and they will appear in the new 9th Edition of the Red Book.

CJS will keep a record of all new changes to guidance made to the 9th Edition of the Red Book.

Post Meeting Note: Changes have been made to the draft text for the 9th Edition of the Red Book received in January 2017.

4.3 **Inclusion of Trial Component Specification in Chapter 8 Evaluation of novel blood components, production processes and blood packs: generic protocols – JPAC 16-78**

ACTION

There has been some confusion over when to use a trial component specification, and therefore SACBC have suggested amendments to Chapter 8 of the Red Book to cover this topic and make it clearer.

JPAC approved this change and it will appear in the new 9th Edition of the Red Book.

Post Meeting Note: Changes have been made to the draft text for the 9th Edition of the Red Book received in January 2017.

4.4 **Validation of Plasma and Platelet Quality Following Pathogen Inactivation – JPAC 16-79**

This was discussed a length and it was agreed that when the work is complete it should go back to SaBTO as the original request for this work had come from them.

It was agreed that JPAC does need to set specific standards, but it should be made clear that these are the minimum standards required.

Next steps:

- Input from SACTTI was required – pathogen kill
- Back to JPAC in March 2017
- Send to PI systems manufacturers for consultation
- Send finished paper to SaBTO

AK

RC

4.5 **Use of male donors for red cells for Intrauterine and Neonatal Exchange transfusions as a TRALI risk-reduction measure – JPAC 16-80**

The practice of using male donors where possible is not captured in the Red book. In order to clarify this point, SACBC have proposed an addition to the wording of the specifications for intrauterine and neonatal exchange transfusions.

JPAC approved the additional wording in the specifications, but that the words “whenever possible” should be used rather than “should” or “must”.

RC

4.6 **Changes to specifications for pathogen-reduced plasma components – JPAC 16-81**

JPAC agreed that the reference to individuals born after 1996, and importation of plasma, should be removed as these components could be used for any patient depending on Blood Service requirements.

It was agreed that with these amendments the changes should go in the new 9th Edition of the Red Book.

RC informed JPAC that the specifications in Chapter 7 of the new edition of the Red Book would be reordered for clarity.

Post Meeting Note: Changes have been made to the draft text for the 9th Edition of the Red Book received in January 2017.

5. **Standing Advisory Committee on Care And Selection Of Donors**

5.1 **Addition of “Clinically Isolated Syndrome” into obligatory deferral for Central Nervous System Disease – WB DSG – JPAC 16-82**

ACTION

JPAC approved this change and a change notification will be issued.

Post Meeting Note: Change Notification No. 3 2017 was issued 31-01-17 and live on the JPAC website 21-02-17.

5.2 Clarify eligibility of female donors who have had IVF treatment with frozen eggs or frozen embryos – WB DSG – JPAC 16-83

SACCSO had submitted this paper regarding the eligibility of female donors having previously had IVF treatment with frozen eggs/embryos as this has caused some confusion at NHSBT.

It was agreed that the background to the current deferral, including the original paper submitted to JPAC previously, should be reviewed. CJS to do a “look back” at the original decision and send to SM in the first instance.

Post Meeting Note: CJS sent information to SM 15 November 2016

The review will include a formal risk assessment.

GMal

5.3 Entry for Hepatitis A – Affected Individual – WB DSG – JPAC 16-84

After discussion it was agreed to remove the “Discretionary” section from this topic and a change notification will be issued.

Post Meeting Note: Change Notification No. 3 2017 was issued 31-01-17 and live on the JPAC website 21-02-17.

5.4 Change to malaria guidance for Cambodia in the Geographical Disease Risk Index – JPAC 16-85

JPAC approved this change and a change notification will be issued.

Post Meeting Note: Resubmitted to JPAC on 9 March 2017.

5.5 Change Notification No 38 Malaria risk in Brunei Darussalam (for information) – JPAC 16-86

JPAC 16-68 had been circulated for information. A change notification was issued on 19 September.

5.6 Change Notification No 41 Tropical Virus Risk – Zika updates – JPAC 16-87

JPAC 16-67 had been circulated for information. A change notification was issued on 19 September.

5.7 Cost estimate for Donor Selection Guidelines (DSG) re-write – JPAC 16-88

and

Validation of Donor Selection Guidelines (DSG) Rewrite – Statistical Analysis – JPAC 16-89

After a long detailed discussion JPAC decided not to take this forward at this time, but that the need for a re-write would be reviewed again at a later date.

SM thanked all those involved, especially the nurses at the WBS and SACCSO, for the enormous amount of work which had been done on this project.

5.8 Draft SaBTO Guidance on the microbiological safety of human organs, tissues

ACTION**and cells used in transplantation (to accompany JPAC 16-83) – JPAC 16-90**

This is a revision to the 2011 document. AC asked JPAC to feedback any comments directly to her.

AK will also circulate to appropriate members of SACTTI for comment.

6. **Standing Advisory Committee on Tissues and Cellular Therapy Products**

6.1 **Malignancy entry in the Deceased Tissue Donor Selection Guidelines – JPAC 16-91**

JPAC approved the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 5 2017 – Malignancy issued 21-02-17 and live on the JPAC website on 24-01-17.

6.2 **Surgery entry in the Bone Marrow and Peripheral Blood Stem Cell, Cord Blood and Living Tissue Donor DSGs – JPAC 16-92**

JPAC approved the recommendation and a change notification will be issued for tissues only.

Post Meeting Note: Resubmitted to JPAC meeting on 09 March 2017.

SF raised an issue with the “Surgery” topic and endoscopy in the Whole Blood Donor Selection Guidelines. He will submit a paper to the next SACCS D meeting in January, which will then come to JPAC in March.

SF

6.3 **Draft Change Notification with regard to Tropical Virus Risk (Zika Virus) – Deceased Tissues Donor Selection Guidelines – to allow risk assessment of valuable products – JPAC 16-93**

Draft Change Notification with regard to Tropical Virus Risk (Zika Virus) – Cord Blood Donor Selection Guidelines – JPAC 16-94

Draft Change Notification with regard to Tropical Virus Risk (Zika Virus) – Tissue Donor Selection Guidelines for Live Tissue Donors and Bone Marrow and PBSC Donor Selection Guidelines – JPAC 16-95

After a long discussion JPAC agreed that this change should only be made to the Stem Cell, Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines. A Change Notification will be issued.

AC

6.4 **Kidney Stones entry in the Cord Blood and Bone Marrow & Peripheral Blood Stem Cell DSGs – JPAC 16-96**

JPAC approved the recommendation and a change notification will be issued.

Post Meeting Note: Change Notification No 7 2017 – Kidney Stones issued 21-02-17 and live on the JPAC website on 24-01-17.

7. **Standing Advisory Committee on Transfusion Transmitted Infections**

7.1 **Position Statement: Dengue Virus: September 2016 – JPAC 16-97**

JPAC approved this updated position statement, which will be posted in the

ACTION

Document Library on the JPAC website.

Post Meeting Note: Position Statement posted on the JPAC website.

7.2 Position Statement: Ebola Virus; September 2016 – JPAC 16-98

JPAC approved this updated position statement, which will be posted in the Document Library on the JPAC website.

Post Meeting Note: Position Statement posted on the JPAC website.

7.3 Position Statement: Arrangements in place for monitoring threats to the UK blood supply from new/emerging infectious agents; September 2016 – JPAC 16-99

AK is meeting with CJS to review the whole process and will report back to the next JPAC in March.

It was noted that the name of JPAC needed to be updated in this paper, but with these minor corrections it has JPAC's approval and will be posted on the JPAC website. The Horizon Scanning MPD will be added as an appendix. (see also item 7.6)

Post Meeting Note: Position Statement posted on the JPAC website.

7.4 Position Statement: West Nile Virus; September 2016 – JPAC 16-100

JPAC approved this updated position statement which will be posted in the Document Library on the JPAC website.

Post Meeting Note: Position Statement posted on the JPAC website.

7.5 Update to Chapter 9 of Red Book Guidelines: removal of requirement for an anti-HBs level of >100 mIU/ml in anti-HBc reactive tissue or stem cell donations which are HBsAg and ID HBV DNA negative – JPAC 16-108

This had been reviewed by SACTTI following a request from SACTCTP.

JPAC approved the recommendation to remove the need for a minimum anti-HBs level in donor/donations which are HBsAg and HBV DNA negative but anti-HBc reactive and the changed text will appear in the new 9th Edition of the Red Book.

AK

7.6 Horizon Scanning process - verbal report

AK gave an update on the Horizon Scanning process and how the system has been working over the last few months. ODT had asked to be included in the monthly telecons and this had been agreed.

As the process has been running for a year it was agreed that AK and CJS would review the system and see if any further improvements can be made.

Post Meeting Note: AK and CJS are meeting in April to review the process.

8. UK BTS Forum

8.1 Report back from the UK Forum meeting on 16 September 2016 – JPAC 16-101

SM went through this report for the group and updated JPAC on the following:

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- MSM deferral in Northern Ireland
- Zika virus
- New CEO in Northern Ireland - Karin Jackson

9. SaBTO**9.1 Report back from the SaBTO meeting on 1 November 2016 – JPAC 16-102**

GMal went through this report from the meeting held on the 1 November to consider the recommendations of the HEV working group report of 25 October 2016.

SaBTO agreed to recommend the introduction of universal testing of blood and blood components for HEV. Also, universal testing would eliminate the logistical difficulties and costs to hospitals and blood services of maintaining dual inventories. Implementation will be decided by each Blood Service.

It was agreed that PHE would provide an annual update on HEV prevalence and need for HEV testing be reviewed in 3 years.

- Proposed dates for SaBTO meetings in 2017
 - Wednesday 18 January
 - Wednesday 19 April
 - Wednesday 20 September

10. Penrose Inquiry – Reflection points for JPAC – JPAC 16-103**10.1** As a result of the Penrose Inquiry Dr Lorna Williamson (former Medical Director of NHSBT) had put together a document looking at how NHSBT are going to mitigate any issues. It was suggested that JPAC should produce something similar.

JPAC 16-103 contains JPAC reflection points. The paper:

- (i) summarises the issues raised
- (ii) describes current JPAC policies that relate to them
- (iii) considers how similar issues arising today would be handled.

As a result JPAC approved the following actions:

- **Section B1 – annual appraisal of members & chairs**
Strengthen the relevant section in the draft JPAC Constitution – at the moment it is voluntary
- **Horizon scanning**
Individual SACs to have this as a standing item at the beginning of each SAC meeting. This could also be another item for the work plans.

The document was approved by JPAC and will be submitted to the next UK Forum meeting in December.

Post Meeting Note: Paper submitted to the UK Forum on 9 December 2016 where it was approved.

11. Zika Virus – update

ACTION
GMAI

GMAI will circulate the final version of the ABO framework to JPAC for information.

12. Draft JPAC Change Notification Process – JPAC 16-104

After discussion JPAC agreed that the current procedures for the Change Notification Process for the Tissues and Cells DSGs and Red Book changes were appropriate and should continue.

SM will feed back this information to MT for SNBTS.

Post Meeting Note: Agenda item 09 March 2017

13. Any Other Business

13.1 SHOT – Relationship with JPAC

To clarify, SM is a member of the SHOT Steering Group representing JPAC and SF represents the UK Forum. SM commented that the importance of the relationship with JPAC is to keep SHOT informed of any changes to UK Blood Service policy particularly with respect to new blood components, and to ensure that recommendations proposed should not impact adversely on Blood Services.

13.2 Commission Directive (EU) 2016/1214

SF informed JPAC that Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments was now available on the europa.eu website.

CJS will email a PDF version of the Directive to JPAC.

Post Meeting Note: Circulated 11-11-16 and also added to the Document Library on the JPAC website.

13.3 Quality Managers Annual Report

This document had been circulated for information and was noted by JPAC.

13.4 Red Book 9th Edition

Following further information from NHSBT, the number of hard copies required is being reviewed again. SM and CJS will liaise with the Blood Services as to how many copies they will require.

SM &
CJS

14. Date & venue for future JPAC meetings

Please note new venue for future meetings

2017

- Thursday 09 March - Boardroom, West End Donor Centre, London
- Thursday 22 June - Boardroom, West End Donor Centre, London
- Thursday 09 November - Boardroom, West End Donor Centre, London

The meeting closed at: 15:15