APPROVED 09/11/2017

Joint UKBTS Professional Advisory Committee

Minutes of the 67th meeting held in the Boardroom at the West End Donor Centre, 26 Margaret Street, London, W1W 8NB on Thursday 22 June 2017

Meeting commenced at: 11:00

Present

Dr Neil Almond	**(NA)**	-	National Institute for Biological Standards and Control *(also deputising for Dr Christian Schneider)*
Dr Stuart Blackmore	**(SB)**	-	Standing Advisory Committee on Care and Selection of Donors
Dr Rebecca Cardigan	**(RC)**	-	Deputy Professional Director of JPAC
Dr Akila Chandrasekar	**(AC)**	-	Standing Advisory Committee on Tissues and Cellular Therapy Products
Dr Stephen Field	**(SF)**	-	Medical Director, Irish Blood Transfusion Service
Dr Alan Kitchen	**(AK)**	-	Standing Advisory Committee on Transfusion Transmitted Infections
Dr Sheila MacLennan	**(SM)**	-	Professional Director of JPAC **(Chair)**
Dr Gary Mallinson	**(GMal)**	-	Scientific Lead Safety Policy (JPAC/SaBTO)
Dr Gail Miflin	**(GM)**	-	Medical Director, NHS Blood and Transplant
Dr Helen New	**(HN)**	-	Standing Advisory Committee on Blood Components
Dr Megan Rowley	**(MR)**	-	Standing Advisory Committee on Clinical Transfusion Medicine
Miss Caroline Smith	**(CJS)**	-	JPAC Manager **(Minute taker)**
Dr Shirley Stagg	**(SS)**	-	Human Tissue Authority (HTA)
Dr Nay Win	**(NW)**	-	Standing Advisory Committee on Immunohaematology

Observer

Mr Ian Rees	**(IR)**	-	Medicines and Healthcare Products Regulatory Agency

SM welcomed HN to her first meeting as Chair of SACBC, RC to her first meeting as Deputy Director of JPAC, SF to his first meeting as the Medical Director of the Irish Blood Transfusion Service and Mr Ian Rees from the MHRA who was presenting item 12 and observing the rest of the JPAC meeting.

ACTION

1. Apologies

Prof John Forsythe	**(JF)**	-	Associate Medical Director – Organ Donation & Transplantation, NHS Blood & Transplant
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
Dr Kieran Morris	**(KM)**	-	Medical Director, Northern Ireland Blood Transfusion Service
Mr David Olszowka	**(DA)**	-	Medicines and Healthcare Products Regulatory Agency

ACTION

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)

2. Minutes of the last meeting held on 09 March 2017 - JPAC 17-50

AC asked for the final sentence in the Minute of item 4.11 to be removed. With this amendment the minutes were approved as a true record of the meeting.

Item 4.9 Decreasing Malaria deferral period

GM asked for feedback on the outcome of the discussion of this at the SACTTI parasitology sub-committee. AK reported that they considered that 4 months' deferral is the minimum safe period and that this should not be reduced further; UK data show clearly that malaria cases may not be identified until 4 months after return from an endemic area. GM asked the rationale behind this decision could be provided in a simple document. It would be useful to put this through the ABO risk assessment framework. **AK and GMal**

3. Matters arising not on the agenda (Review of actions list) JPAC 17-51

3.1 Perfusion of organs – item 3.1

This is now on the SACBC work plan and will be removed from the JPAC actions list.

3.2 Validation of Plasma and Platelet Quality Following Pathogen Inactivation – JPAC 16-79 – item 3.2

AK will take the comments back to SACTTI and this will come back to JPAC in November

Post Meeting Note: Submitted to the JPAC meeting on 09 November 2017.

3.3 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 – item 3.6

No further action is required at this time, but will come back to JPAC if required. It was agreed that this should now be removed from the JPAC actions list.

3.4 Estimated risk of a Zika infected blood component being transfused to a 'risk' recipient - updated 20 February 2017 – JPAC 17-11 – item 4.8

GMal will circulate the updated tissues document.

Post Meeting Note: Circulated 04 August 2017.

ACTION

3.5 Risk Assessment: Toxoplasmosis – version 5 – JPAC 17-14 – item 4.11

Post Meeting Note: Submitted to the JPAC meeting on 09 November 2017.

3.6 Review of current and proposed new concessionary release limits for blood components – JPAC 17-21 – item 6.1

RC informed JPAC that this had been completed.

3.7 Remanufacture of CDP red cell units – JPAC 17-22 – item 6.2

RC informed JPAC that this had been completed.

3.8 Effect of irradiation on platelet function – JPAC 17-24 – item 6.4

No further action required. RC did forward this paper to BCSH and it has been to SaBTO.

3.9 Change to pH specification for Platelets for Neonatal Use, Leucocyte Depleted – JPAC 17-26 – item 6.6

Complete.

3.10 Change to the definition for Surgery which applies to the Tissue Donor Selection Guidelines for Live Tissue Donors, Cord Blood Donors and Bone Marrow & Peripheral Blood Stem Cell Donors – JPAC 17-29 – item 7.2

Post Meeting Note: Change Notification No 24 issued.

3.11 Ingestion of substances prior to donation – item 16.2

This item will be submitted to the JPAC meeting in November. **AC**

4 Standing Advisory Committee on Care and Selection of Donors

4.1 Review of Drug Index in the Whole Blood and Components Donor Selection Guidelines – JPAC 17-52

The drugs listed in the "non-steroidal anti-inflammatory drugs" section of the on-line BNF has been compared with the Drug Index in the Whole Blood and Components section of the JPAC website. Additional drug names need to be added to the JPAC Drug Index. JPAC approved the updated list and a Change Notification will be issued.

Post Meeting Note: Change Notification No. 19 2017 Drug Index was issued 24 August 2017.

4.2 Position Statement on Calcium Abnormalities and Apheresis Donation – JPAC 17-53

JPAC approved the updated Position Statement but requested that the highlighted sentence should be expanded to include more details about the quoted study. With this amendment, the Position Statement will be posted in the Document Library on the JPAC website.

Post Meeting Note: This updated Position Statement has been posted on the JPAC website.

4.3 Thyroid Disease entry in the Whole Blood and Components Donor Selection

ACTION

Guidelines – JPAC 17-54

JPAC 17-54 is a review of the Thyroid disease entry. After discussion around deferral periods JPAC approved the paper with the following amendments:

Under Obligatory

e) Less than 8 weeks since commencing thyroid replacement therapy (thyroxine)

and under Discretionary

If on stable maintenance thyroid replacement therapy (thyroxine) and there have been no dose changes in the last 4 weeks, accept.

With this amendment, a change notification will be issued.

Post Meeting Note: Change Notification No. 18 2017 Thyroid Disease was issued on 24 August 2017.

AC will check whether this also applies to the TDSGs so that one notification can be issued to cover all the guidelines. **AC**

4.4 Zika and Dengue updates in the Geographical Disease Risk Index (GDRI) – JPAC 17-55

Following the publication of the WHO updated Zika country classifications several countries have been identified that need Zika virus and Dengue Virus adding to the Tropical Virus Risk in the GDRI. JPAC approved this update and a change notification will be issued

Post Meeting Note: Change Notification No. 20 2017 Tropical Virus Disease was issued on 24 August 2017.

5. Standing Advisory Committee on Immuno-Haematology

5.1 Pooled platelets prepared in platelet additive solution (PAS) and high titre (HT) haemolysin testing – JPAC 17-56

This was discussed at length. It was noted that this does not affect the guidelines in the Red Book or the specification for PAS pooled platelets.

HN commented that the number of components tested was small. NW will discuss with a statistician whether an increased number need to be tested. **NW**

JPAC endorsed the recommendations in the paper, subject to statistical advice and further testing if appropriate, and the following actions were agreed:

- MR will discuss with Marc Turner and make sure that there are no issues for SNBTS. **MR**
- SF will discuss with WBS and Joan Jones. **SF**
- SHOT needs to be informed
- May affect BCSH so need to be informed **SM**
- Medical Directors need to think how they are going to promulgate this in each Service. **GM, MT & KM**

ACTION

6. Standing Advisory Committee on Blood Components

6.1 Rejuvenated red cells – Trial component specification – JPAC 17-57-A

Confidential

RC spoke to this paper.

The paper has been produced for JPAC to summarise the evidence in support of using rejuvenated red cells as a trial component. It was noted that this is a Class 2b device, therefore the MHRA do not require NHSBT to alter their licence. It is not CE marked, but it does have FDA approval.

This paper has already been reviewed by SACBC, SACIH, SACTTI and NHSBT's Therapeutic Products Safety Group.

SM thanked those involved for this extraordinarily comprehensive piece of work which covers all bases.

JPAC approved the draft trial specification, which would be posted in the "Trial Components" section on the JPAC website and the progression to the clinical study subject to confirmation in operational validation that the component complies with this specification.

Post Meeting Note: Trial Component A3.4 Red Cells, Rejuvenated and Washed, Leucocyte Depleted is now available on the JPAC website – Red Book, Annex 3.

6.2 Figures for rejuvenated red cells – Trial component specification – JPAC 17-57-B

See item 6.1 above.

6.3 Review of UK blood services' blood component leucocyte depletion performance from 2010 to 2017 - Quarter 1 – JPAC 17-58

HN spoke to this paper. The findings were noted with interest and the authors were encouraged to consider publication.

6.4 Use of transfusion administration sets in conjunction with blood components and removal of statement regarding microaggregate filter (screen) pore size – JPAC 17-59

JPAC approved the recommendations in the paper. SM will take to the next meeting of the Council of Europe. HN has already alerted the authors of the BSH Administration guidelines which are in draft. Any reference to filter size in the Red Book will be amended in the new 9th edition. **SM / HN**

6.5 Supernatant free haemoglobin (SNHb) as product release criterion for frozen and recovered red cells – JPAC 17-60

This is an improvement in quality and a tighter specification. JPAC approved the paper and a change notification will be issued. **HN**

7. Standing Advisory Committee on Transfusion Transmitted Infections

7.1 Dengue Virus Risk Assessment – V7 – JPAC 17-61

ACTION

JPAC approved this updated risk assessment for Dengue and noted that no changes to the current donor selection guidelines were required.

7.2 Hepatitis E Virus Risk Assessment – V3 – JPAC 17-62

This is an updated risk assessment for Hepatitis E based on additional information now available.

As universal screening is being implemented JPAC approved the recommendation that no further updates are required whilst the UK Blood Services are performing universal screening of donors/donated products.

7.3 Zika Virus Risk Assessment – V2 – JPAC 17-63

JPAC approved this updated risk assessment for the Zika Virus and that, for the time being, it should still be reviewed annually. If imported cases drop then this would be looked at again and possibly go to a 2-year review period.

7.4 Zika Virus Position Statement – June 2017 – JPAC 17-64

JPAC approved the position statement which has been updated taking into account the updated risk assessment, the current case numbers for the UK and the significant amount of work that has been undertaken by many groups to better understand Zika virus and the consequences of infection. This updated version will be posted on the JPAC website

Post Meeting Note: This updated Position Statement has been posted on the JPAC website.

7.5 Chapter 9 of the Red Book – Microbiology tests for donors and donations: general specifications for laboratory test procedures – JPAC 17-65

Section 9.2.2 was discussed and AC agreed to send AK appropriate wording. **AC**

9.2.2. Deceased neonatal and infant tissue donors

- Full microbiology screening of a maternal sample is always required

With this change, JPAC approved the new Chapter 9 which will appear in the 9th Edition of the Red Book. **AK**

7.6 Chapter 10 of the Red Book - Investigation of suspected transfusion-transmitted infection – JPAC 17-66

JPAC approved the minor changes to Chapter 10, which will appear in the 9th Edition of the Red Book. **AK**

7.7 Alan Kitchen – Retiring Chair of the SAC on Transfusion Transmitted Infection

On behalf of JPAC, SM thanked AK for all his hard work and support as Chair of the SACTTI since March 2014. JPAC was please that he will, however, be continuing as a member of SACTTI.

8. Standing Advisory Committee on Tissues and Cellular Therapy Products

8.1 Age limit for hearts donated for allografts – JPAC 17-67

JPAC approved this simplification of the entry and a change notification will be issued.

ACTION

Post Meeting Note: Change Notification No. 21 2017 Age issued

8.2 Eligibility of donors that have had radiation therapy for in situ carcinoma of the breast – JPAC 17-68

JPAC approved this change which is to keep guidelines for tissues and cells in line with those for whole blood and components and a change notification will be issued.

Post Meeting Note: Change Notification No. 22 2017 Radiation Therapy issued

8.3 Tissue and organ recipients – JPAC 17-69

JPAC approved this recommended amendment to the Tissue and Organ Recipients entry and a change notification will be issued.

Post Meeting Note: Change Notification No. 23 2017 Tissue and Organ Recipients issued

9. Standing Advisory Committee on Clinical Transfusion Medicine

9.1. 6th Edition of the Handbook of Transfusion Medicine – JPAC 17-71

JPAC supports the recommendation to consider moving to an on-line publication only of the handbook and that a survey of users should be undertaken. JPAC requested that the wording of question 6 in the survey should be modified to include the possibility that if hard copies are produced they may have to be purchased by users. **MR**

10. UK BTS Forum

10.1 Report back from the UK BTS Forum meetings on 24 March and 02 June 2017 – JPAC 17-72

1) 24 March 2017

a) JPAC work plan approved

b) JPAC Constitution approved

c) Red Book 9th Edition – online publication only approved

2) 02 June 2017

GTS meeting April 2018 – supported the UKs hosting of this meeting, which was last held in the UK in 2003.

11. SaBTO

11.1. SaBTO update – Gary Mallinson

SaBTO met on the 9th June 2017. The report from the SaBTO donor selection criteria working group was endorsed by SaBTO and the recommendations will now go to Ministers at the Department of Health and the devolved administrations before the parliamentary recess in July. It is hoped that the UK blood services will implement the changes to donor selection criteria at the same time; it will be at least Jan 2018 before any changes are made to allow adequate preparation of donor selection guidelines.

ACTION

A discussion paper on the importation of plasma for patients born after 1995 as a risk reduction measure for vCJD was presented to SaBTO. The committee was asked if this matter should be reviewed as the cohort of recipients was increasing year on year and there were difficulties in securing a long-term supply of plasma from countries with a low risk of vCJD. There were also concerns about the operational consequences of running a dual inventory for adult hospital services. The committee was informed of further work being carried out to try to interpret the recent Appendix III data which could lead to a better assessment of the risk of transmission of vCJD from blood. It was felt that this matter required further consultation with stakeholders and a proposal should be brought to the next meeting.

SaBTO approved the updated Microbiological Safety Guidelines which had been revised after stakeholder consultation, the guidelines will be published and NHSBT will use its networks to distribute the revised guidelines.

Post-Meeting Note: Some of the UK Blood Services may be able to implement changes to the guidelines sooner than this timescale

12. Europe: Commissions' Joint Action on Preparation Process Authorisation

12.1 Joint action 2016 on "Authorisation of preparation processes in blood and tissues and cells" – JPAC 17-73
A new Joint action on "Authorisation of preparation processes in blood and tissues and cells" *(copy of PowerPoint presentation)* – JPAC 17-74

Papers JPAC 17-73 and 17-74 were presented by Mr Ian Rees (IR) from the MHRA.

- This will be a 3-year project and the Commission are keen to get the UK involved.
- HTA are planning to be an associate partner on sections 5, 6 and 7.
- JPAC are happy to collaborate with the MHRA as and when required.
- IR will contact SM once the MHRA have started mapping out dates and time lines.

13. Evaluation of the EU Directives on Blood, Tissues and Cells

13.1 Evaluation of the EU legislation on Blood, Tissues and Cells – JPAC 17-75
Announcement of stakeholder consultation – JPAC 17-76
Blank questionnaire to be completed – JPAC 17-77
Summary of changes requested from SAC Chairs – JPAC 17-78

SM is coordinating the UK joint response at the request of the UK Forum and will share with MHRA and HTA.

14. Change Notification Process: Tissues and Cells

14.1 Review of the Change Notification process for tissues and cells – JPAC 17-79

JPAC approved the process suggested in paper JPAC 17-79.

MT had emailed CJS and Emily Hargreaves (Quality Department at SNBTS) thanking them for their work on putting together this process for the tissues and cells

ACTION

changes.

15. Any Other Business

15.1 SAC meeting papers and minutes

GMal requested that all SAC Chairs add him to their contact lists for SAC papers and minutes and also asked them to get in touch with regard to any help required.

Date & venue for future JPAC meetings

- Thursday 09 November - Boardroom, West End Donor Centre, London

2018

- Thursday 08 March - Boardroom, West End Donor Centre, London
- Thursday 28 June - Boardroom, West End Donor Centre, London
- Thursday 08 November - Boardroom, West End Donor Centre, London

The meeting closed at: 15:06